File No. 7342

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

APPLICANT:	Al Najjar	**GROUP:**	Unknown
SERIAL NO:	10/706,790	**EXAMINER:**	George M. Dombroske
FILED:	11/12/2003		
FOR:	ARTIFICIAL HEART		

Mail Stop PCT
Commissioner of Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

RENEWED PETITION UNDER 37 C.F.R. §1.137(b)

In response to the Decision On Petition Under 37 C.F.R. 1.137(b) mailed December 17, 2003, we hereby respectfully request the Examiner to reconsider our previously submitted request for Revival of a Patent Abandoned Unintentionally Under 37 C.F.R. §1.137(b).

The Petition was denied on the grounds that a grantable petition must be accompanied by (1), the applicant has not filed the required reply in the form of the basic national fee.

In response, we enclose true copies of the following all of which were filed on November 12, 2003:

- USPTO stamped post card;

CERTIFICATE OF EXPRESS MAIL UNDER 37 C.F.R. §1.10

I hereby certify that this Petition and the documents referred to as enclosed therein are being deposited with the United States Postal Service on January 23, 2004 in an envelope as "Express Mail Post Office to Addressee" Mailing Label Number EV383579521US addressed to the: Mail Stop PCT, Commissioner of Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

Emily C. Porell

Emily C. Porell

- Express Mail Label EL960883183US stamped by the U.S. Post Office November 12, 2003;

-Checks in the amount of $385.00 for the National Filing fee and $665.00 for the Petition Fee;

- New U.S. Patent Application for ARTIFICIAL HEART (28 pgs.);

- Added Pages for Application Transmittal Where Benefit of Prior U.S. Application(s) Claimed;

- Petition for Revival of a Patent Abandoned Unintentionally Under 37 C.F.R. §1.137(b);

- Preliminary Amendment;

- Information Disclosure Statement and Form PTO-1449;

- Copy of International Publication No. WO 02/085432;

- Copy of International Search Report;

- Copy of International Preliminary Examination Report;

- Copy of PCT Request;

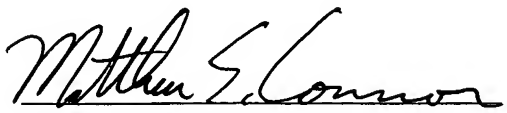
- Copy of PCT/IB/332;

- Copy of PCT/IB/308.

Also enclosed, please find copies of the returned checks which we received from our banking institution showing deposit by the United States Patent and Trademark Office.

In view of the forgoing, we respectfully request that the Petition be reconsidered by the Examiner.

Respectfully submitted,



Matthew E. Connors
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Gauthier & Connors
225 Franklin Street, Suite 3300
Boston, Massachusetts 02110
Telephone: (617) 426-9180
Extension: 112

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SAMUELS, GAUTHIER & STEVENS LLP
225 FRANKLIN STREET - SUITE 3300
BOSTON, MASS. 02110

5-7017/2110

11/7/2003

$385.00

Three Hundred Eighty Five Dollars And 00 Cents

Commissioner of Patents

MP

SECURITY FEATURES INCLUDED. DETAILS ON BACK.

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ENT=3729 TRC=3749 PK=10

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WILSON NC 27893 11192003
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13-10-0001
11-18-2003
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11/7/2003

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Matthew E. Connors MP

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MELLON TR ME 7253-44/25/03

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031107(7342)	11/7/2003	$385.00	$385.00	$0.00	$385.00
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⑈014069⑈ ⑆211070175⑆ 110784842 0⑈

COPY

Mailed on November 12, 2003 Strom.7342
Express Mail No. EL960883183US
Enclosed please find the following:

1) New U.S. Patent Application for
ARTIFICIAL HEART
Pgs: 28/ Spec., Clms. & Abst.: 15/ Dwgs.: 12./ Coversheet: 1/
2) New Application Transmittal
3) Added Pages For Application Transmittal Where Benefit Of Prior U.S. Application(s) Claimed
4) Petition for Reival of a Patent Abandoned Unintentionally Under 37 CFR 1.137(b)
5) Preliminary Amendment
6) Information Disclosure Statement
7) Form PTO-1449 and copy of foreign cited patent with English Abstract
8) Copy of Int'l Publication No. WO 02/085432
9) Copy of International Search Report
10) Copy of International Preliminary Examination Report
11) Copy of PCT Request
12) Copies of Form PCT/IB/332 & PCT/IB/308
13) $385.00 check for filing fee & $665.00 check for revival fee

PLEASE PROVIDE US WITH
SERIAL NO. & FILING DATE

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031283 U.S. PTO
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C OF P	Commissioner of Patents	00000000000008008	11/7/2003	14070	
031107(7342 REV)	11/7/2003	$665.00	$665.00	$0.00	$665.00
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225 FRANKLIN STREET - SUITE 3300
BOSTON, MASS. 02110

5-7017/2110
11/7/2003

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Six Hundred Sixty Five Dollars And 00 Cents

Commissioner of Patents

Matthew E. Connors MP

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Weight: 1 lbs. 2 ozs.	Int'l Alpha Country Code	COD Fee / Insurance Fee
No Delivery: ☐ Weekend ☐ Holiday	Acceptance Clerk Initials: AVE	Total Postage & Fees: $ 17.85

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TO: (PLEASE PRINT) PHONE ( )

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MAIL STOP: PATENT APPLICATION

PRESS HARD.
You are making 3 copies.

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NEW APPLICATION TRANSMITTAL

Transmitted herewith for filing is the patent application of:

Inventor(s): Azaz Al-Najjar

For (title): ARTIFICIAL HEART

1. **Type of Application**
   - ☒ Utility
   - ☐ Design

2. **Small Entity**
   - ☒ Yes
   - ☐ No

3. **Benefit of Prior U.S. Application(s) Under 35 U.S.C. §120**

This application is a:
- ☐ Divisional
- ☒ Continuation
- ☐ Continuing Patent Application (CPA) under 37 C.F.R. §1.53(d)
- ☐ Continuation-in-part (CIP),

and hereby claims benefit under 35 U.S.C. §120 to the following applications:

SERIAL NUMBER	FILING DATE
PCT/SE02/00689	4/8/02

4. **Benefit of Non-U.S. Application Under 35 U.S.C. §119(a)-(d)**

This application claims priority under 35 U.S.C. §119(a)-(d) to the following foreign application(s) and/or inventor certificate(s):

COUNTRY	APPLN. NUMBER	FILING DATE
Sweden	0101259-0	4/10/01

Certified copy(ies) of the application(s) and/or inventor certificate's from which priority is claimed:
- ☐ is(are) attached;
- ☒ will follow.

CERTIFICATE OF EXPRESS MAIL UNDER 37 C.F.R. §1.10

I hereby certify that this New Application Transmittal and the documents referred to as enclosed therein are being deposited with the United States Postal Service on November 12, 2003 in an envelope as "Express Mail Post Office to Addressee" Mailing Label Number EL960883183US addressed to the: Mail Stop Patent Application, Commissioner of Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

Deborah M. Costello

5. **Benefit of Provisional Application Under 35 U.S.C. §119(e)**

This application claims priority to the following provisional application(s):

SERIAL NUMBER	FILING DATE
None	

6. **Papers Enclosed Which Are Required For Filing Date Under 37 C.F.R. §1.53**

16 Pages of Specification, including cover sheet, claims, and abstract

12 Sheets of Drawing

7. **Additional Papers Enclosed**

- ☐ Declaration and Power of Attorney
- ☒ Preliminary Amendment
- ☒ Information Disclosure Statement (37 CFR 1.98), Form PTO-1449 and a copy of cited article references
- ☐ Assignment and Form PTO-1595
- ☐ Declaration of Biological Deposit
- ☐ Submission of "Sequence Listing" computer readable copy and/or amendment pertaining thereto for biotechnology invention containing nucleotide and/or amino acid sequences.
- ☒ Petition For Revival Of A Patent Abandoned Unintentionally Under 37 CRF 1.137(b) along with $665.00 check for fee

8. **Application Filing Fee Calculation**

A. ☒ Utility Application

FEE CALCULATION:

Total Claims: 8 - 20 = × $18 =$

Independent Claims: 1 - 3 = 1 × $86 =$

Basic Fee: ..$770.00

Multiple-Dependent-Claim Fee : ..$

Total of the Above Calculations: $770.00

- ☐ Amendment canceling extra claims enclosed.
- ☒ Amendment deleting multiple dependencies enclosed.
- ☐ Fee for extra claims is not being paid at this time.

B. ☐ Design application - $320 $

Application Filing Fee Sub-Total ..... $

C. ☐ Less 50% reduction for small entity..... $285.00

D. ☐ Non-English Specification - $130..... $

TOTAL FILING FEE $385.00

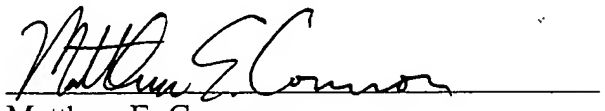
9. **Payment**

☒ Enclosed

- ☒ Check in the amount of the Total Filing Fee set forth above.
- ☐ Charge Account No. 19-0079 in the amount of Total Filing Fee set forth above. A duplicate of this transmittal is attached.

☐ Not Enclosed

Respectfully submitted,



Matthew E. Connors
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Samuels, Gauthier & Stevens LLP
225 Franklin Street, Suite 3300
Boston, MA. 02110
(617) 426-9180, Ext. 112

ADDED PAGES FOR APPLICATION TRANSMITTAL WHERE BENEFIT OF PRIOR U.S. APPLICATION(S) CLAIMED

NOTE: "In order for an application to claim the benefit of a prior filed copending national application, the prior application must name as an inventor at least one inventor named in the later filed application and disclose the named inventor's invention claimed in at least one claim of the later filed application in the manner provided by the first paragraph of 35 U.S.C. 112." 37 CFR 1.78(a).

NOTE: "In addition the prior application must be (l) complete as set forth in ' 1.51, or (2) entitled to a filing date as set forth in ' 1.53(b) and include the basic filing fee set forth in ' 1.16; or (3) entitled to a filing date as set forth in ' 1.53(b) and have paid therein the processing and retention fee set forth in ' 1.21(1) within the time period set forth in ' 1.53(d)." 37 CFR 1.78(a).

9. Relate Back--35 U.S.C. 120

NOTE: "Any application claiming the benefit of a prior filed copending national or international application must contain or be amended to contain in the first sentence of the specification following the title a reference to such prior application identifying it by serial number and filing date or international application number and international filing date and indicating the relationship of the applications." 37 CFR 1.78(a). See also the Notice of April 28, 1987 (1079 O.G. 32 to 46).

X Amend the Specification by inserting before the first line the sentence:

"This is a

x continuation
__ continuation-in-part
__ divisional

of copending application(s)

__ serial number _____ filed on _____"

X International Application PCT/SE02/00689 filed on 8 April 2002 and which designated the U.S."

NOTE: The proper reference to a prior filed PCT application which entered the U.S. national phase is the U.S. serial number and the filing date of the PCT application which designated the U.S.

NOTE: (1) Where the application being transmitted adds subject matter to the International Application then the filing can be as a continuation-in-part or (2) it is desired to do so for other reasons, e.g. where no declaration is available, no English translation is available or no fee is to be paid on filing then the filing can be as a continuation. In these cases the International Application designating the U.S. is treated as the parent case in the U.S. and is an alternative to the completion of the International Application under 35 U.S.C. 371(c)(4) which must meet the requirements of 37 CFR 1.61(a). This alternative permits the completion of the filing requirements within any term set by the PTO under 37 CFR 1.53(d) to which the extension provisions of 37 CFR 1.136(a) apply. (Whereas, if the filing is as an international application entering the U.S. stage then the fee, declaration and/or English translation (where necessary) is due within 20 months of the priority date but can be paid within 22 months of the priority date (or is due within 30 months of the priority date but can be submitted within 32 months of the priority date) with the surcharges set forth in 37 CFR 1.492(e), (f) and 37 CFR 1.495(c); however, the provisions of 37 CFR 1.136 do not apply to this 22 or (32 month) period. 37 CFR 1.61(b).)

NOTE: The deadline for entering the national phase in the U.S. for an international application was clarified in the Notice of April 28, 1987 (1079 O.G. 32 to 46) as follows:

"The Patent and Trademark Office considers the International application to be pending until the 22nd month from the priority date if the United States has been designated and no Demand for International Preliminary Examination has been filed prior to the expiration of the 19th month from the priority date and until the 32nd month from the priority date if a Demand for International Preliminary Examination which elected the United States of America has been filed prior to the expiration of the 19th month from the priority date, provided that a copy of the international application has been communicated to the Patent and Trademark Office within the 20 or 30 month period respectively. If a copy of the international application has not been communicated to the Patent and Trademark Office within the 20 or 30 month period respectively, the international application becomes abandoned as to the United States 20 or 30 months from the priority date respectively. These periods have been placed in the rules as paragraph (h) of ' 1.494 and paragraph (i) of ' 1.495. A continuing application under 35 U.S.C. 365(c) and 120 may be filed anytime during the pendency of the international application.

CERTIFICATE OF EXPRESS MAIL UNDER 37 C.F.R. §1.10

I hereby certify that this New Application Transmittal and the documents referred to as enclosed therein are being deposited with the United States Postal Service on November 12, 2003 in an envelope as "Express Mail Post Office to Addressee" Mailing Label Number EL960883183US addressed to the: Mail Stop Patent Application, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

Deborah M. Costello

10. Relate Back--35 U.S.C. 119 Priority Claim for Prior Application

The prior U.S. application(s), including any prior International Application designating the U.S., identified above in item 17, in turn itself claim(s) foreign priority (ies) as follows:

Sweden	0101259-0	10 April 2001
country	appln. no.	filed on

The certified copy (ies) has (have)

__ been filed on _____ in prior application 0_/_____ filed on which was filed on _____.

__ is (are) attached

WARNING: The certified copy of the priority application which may have been communicated to the PTO by the International Bureau may **not** be relied on without any need to file a certified copy of the priority application **in the continuing application.** This is so because the certified copy of the priority application communicated by the International Bureau is placed in a folder and is not assigned a U.S. serial number unless the national stage is entered. Such folders are disposed of if the national stage is not entered. Therefore such certified copies may not be available if needed later in the prosecution of a continuing application. An alternative would be to physically remove the priority documents from the folders and transfer them to the continuing application. The resources required to request transfer, retrieve the folders, make suitable record notations, transfer the certified copies, enter and make a record of such copies in the Continuing Application are substantial. Accordingly, the priority documents in folders of international applications which have not entered the national stage may not be relied on. Notice of April 28, 1987 (1079 O.G. 32 to 46).

11. Maintenance of Copendency of Prior Application

NOTE: The PTO finds it useful if a copy of the petition filed in the prior application extending the term for response is filed with the papers constituting the filing of the continuation application. Notice of November 5, 1985(1060 O.G. 27).

A. __ Extension of time in prior application

(This item must be completed and the papers filed in the prior application if the period set in the prior application has run)

__ A petition, fee and response extends the term in the pending prior application until

__ A copy of the petition filed in prior application is attached

B. __ Conditional Petition for Extension of Time in Prior Application

(complete this item if previous item not applicable)

__ A conditional petition for extension of time is being filed in the pending prior application.

__ A copy of the conditional petition filed in the prior application is attached

12. Further Inventorship Statement Where Benefit of Prior Application(s) Claimed

NOTE: "If the continuation, continuation-in-part, or divisional application is filed by less than all the inventors named in the prior application a statement **must** accompany the application when filed requesting deletion of the names of the person or persons who are not inventors of the invention being claimed in the continuation, continuation-in-part, or divisional application. " 37 CFR 1.62(a) [emphasis added]. (dealing with the file wrapper continuation situation).

NOTE: "In the case of a continuation-in-part application which adds and claims additional disclosure by amendment, an oath or declaration as required by ' 1.63 must be filed. In those situations where a new oath or declaration is required due to additional subject matter being claimed, additional inventors may be named in the continuing application. In a continuation or divisional application which discloses and claims only subject matter disclosed in a prior application, no additional oath or declaration is required and the application must name as inventors the same or less than all the inventors in the prior application." 37 CFR 1.60(c). (dealing with the continuation situation).

(complete applicable item (a), (b) and/or (c) below)

(a) _x_ This application discloses and claims only subject matter disclosed in the prior application whose particulars are set out above and the inventor(s) in this application are

_x_ the same

__ less than those named in the prior application and it is requested that the following inventor(s) identified for the prior application be deleted:

(Type name(s) of inventor(s) to be deleted)

(b) __ This application discloses and claims additional disclosure by amendment and a new declaration or oath is being filed. With respect to the prior application the inventor(s) in this application are

__ the same

__ the following additional inventor(s) have been added

(Type name(s) of inventor(s) to be added)

(c) The inventorship for all the claims in this application are

_x_ the same

__ not the same, and an explanation, including the ownership of the various claims at the time the last claimed invention was made

__ is submitted
__ will be submitted

13. Abandonment of Prior Application (if applicable)

__ Please abandon the prior application at a time while the prior application is pending or when the petition for extension of time or to revive in that application is granted and when this application is granted a filing date so as to make this application copending with said prior application.

NOTE: According to the Notice of May 13, 1983 (103, TMOG 6-7) the filing of a continuation or continuation-in-part application is a proper response with respect to a petition for extension of time or a petition to revive and should include the express abandonment of the prior application conditioned upon the granting of the petition and the granting of a filing date to the continuing application.

14. Petition for Suspensi. . of Prosecution for the Time Necessary to F.. an Amendment

WARNING: "The claims of a new application may be finally rejected in the first Office action in those situations where (1) the new application is a continuing application of, or a substitute for, an earlier application, and (2) all the claims of the new application (a) are drawn to the same invention claimed in the earlier application, and (b) would have been properly finally rejected on the grounds of art of record in the next Office action if they had been entered in the earlier application." MPEP, ' 706.07(b).

NOTE: Where it is possible that the claims on file will give rise to a first action final for this continuation application and for some reason an amendment cannot be filed promptly (e.g., experimental data is being gathered) it may be desirable to file a petition for suspension of prosecution for the time necessary.

(check the next item, if applicable)

__ There is provided herewith a Petition To Suspend Prosecution for the Time Necessary to File An Amendment (New Application Filed Concurrently)

15. NOTIFICATION IN PARENT APPLICATION OF THIS FILING

__ A notification of the filing of this

(check one of the following)

__ continuation

__ continuation-in-part

__ divisional

is being filed in the parent application from which this application claims priority under 35 USC . 120.

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

APPLICANT:	Azad Al-Najjar	**GROUP:**	Unknown
SERIAL NO:	Unknown	**EXAMINER:**	Unknown
FILED:	Herewith		
FOR:	**ARTIFICIAL HEART**		

Mail Stop Patent Application
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450
Sir:

PRELIMINARY AMENDMENT

Preliminary to examination, please amend the above-identified application as follows:

IN THE CLAIMS:

Please amend the following claims:

1. (Amended) A heart prosthesis/artificial heart comprising a series of drawing and pressing means and intended to be implanted in a patient to replace the pumping activity of a heart, whereby comprises at least tow compartments [~~(5, 6, 12, 13, 25, 26, 27, 28)~~], substantially surrounded by rigid-wall provided house [~~(2, 3, 31)~~] containing a number of drawing and/or pressing devices [~~(10, 48, 50)~~], [~~characterized in that~~] wherein it comprises two halves, comprising an atrium [~~(25, 26)~~], and ventricles [~~(27, 28)~~] respectively, separated with a valve [~~(29, 40)~~] provided plate [~~(37)~~] which plate [~~(37)~~] is arranged to be able to be moved between the ventricles [~~(27, 28)~~] and the atriums [~~(25, 26)~~] by means of drawing and/or pressing devices [~~(48, 50)~~] arranged in said rigid wall provided house [~~(31)~~].

2. (Amended) A heart prosthesis according to claim 1, [~~characterized in that~~] wherein it comprises four compartment [~~(5, 6, 12, 13, and 25, 26, 27, 28, respectively)~~].

3. (Amended) A heart prosthesis according to claim 1, [~~characterized in that~~] wherein the drawing and/or pressing devices [~~(10, 48, 50)~~] are drawing and pressing electromechanical devices, respectively, including electro-magnets.

4. (Amended) A heart prosthesis according to claim 1, [~~characterized in that~~] wherein said plate [~~(37)~~] is arranged to be moved by means of electro-magnets [~~(48)~~] or a hydraulic device arranged in said wall [~~(31)~~].

5. (Amended) A heart prosthesis according to claim 1, [~~characterized in that~~] wherein the

drawing and/or pressing devices are drawing, and pressing, respectively, hydraulically activated pistons.

6. (Amended) A heart prosthesis according to claim 1, [~~characterized in that~~] wherein it is arranged to be controlled digitally via a soft-ware present in a circuit board [~~(22)~~] in a diastole, atrium systole, and systole phase, respectively.

7. (Amended) A heart prosthesis according to claim 1, [~~characterized in that~~] wherein it is supplied with energy from one or more DC batteries.

REMARKS

The present Preliminary Amendment is submitted in order to conform the claims to U.S. patent practice.

Examination on the merits is respectfully requested.

Respectfully submitted,

Matthew E. Connors
Registration No. 33,298
Samuels, Gauthier & Stevens LLP
225 Franklin Street, Suite 3300
Boston, Massachusetts 02110
Telephone: (617) 426-9180
Extension 112

PETITION FOR REVIVAL OF A PATENT ABANDONED UNINTENTIONALLY UNDER 37 CFR 1.137(b)

First named inventor: Azaz Al-Najjar

International Appln. No.: PCT/SE02/00689 International Filing Date: 4/8/02

Application No.: Unknown Group Art Unit: Unknown

Filed: Herewith Examiner: Unknown

Title: ARTIFICIAL HEART

Attention: Office of Petitions
Assistant Commissioner for Patents
P.O. Box 1450, Alexandria, VA 22313-1450

NOTE: If information or assistance is needed in completing this form, please contact Petitions Information at (703) 305-9282.

The above-identified application became abandoned for failure to file a timely and proper reply to a notice or action by the Patent and Trademark Office. The date of abandonment is the day after the expiration date of the period set for in reply in the Office notice or action plus any extensions of time actually obtained.

APPLICANT HEREBY PETITIONS FOR REVIVAL OF THIS APPLICATION

NOTE: A grantable petition requires the following items:

(1) Petition fee;
(2) Reply and/or issue fee;
(3) Terminal disclaimer with disclaimer fee -- required for all utility and plant applications filed before June 8, 1995; and
(4) Statement that the entire delay was unintentional.

I hereby certify that this paper (along with any paper referred to as being attached or enclosed) is being deposited with the United States Postal Service on the date shown below with sufficient postage as first class mail in an envelope addressed to the Commissioner of Patents and Trademarks, P.O. Box 1450, Alexandria, VA 22313-1450.

Deborah M. Costello

Name: Deborah M. Costello

Date: 11/12/03

1. Petition Fee

☒ Small entity - Fee $ 650.00 (37)CFR 1.17(m)

☐ Small entity statement enclosed herewith.

☐ Small entity statement previously filed.

☐ Other than small entity - fee $_____(37 CFR 1.17(m))

2. Reply and/or fee

A. The reply and/or fee to the above-noted U.S. National Phase Filing in the form of International Application_____(identify type of reply):

☐ has been filed previously on _____.

☒ is enclosed herewith.

B. The issue fee of $

☐ has been paid previously on _____.

☐ is enclosed herewith.

3. Terminal disclaimer with disclaimer fee

☒ Since this utility/plant application was filed on or after June 8, 1995, no terminal disclaimer is required.

☐ A terminal disclaimer (and disclaimer fee (37 CFR 1.20(d)) of $ for a small entity of $_____ for other than a small entity) disclaiming a period equivalent to the period of abandonment is enclosed herewith (see PTO/SB/63).

4. Statement. The entire delay in filing the required reply from the due date for the required reply until the filing of a grantable petition under 37 CFR 1.137(b) was unintentional.

Date:

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Enclosures:

- ☒ Fee Payment
- ☒ Reply
- ☐ Terminal Disclaimer Form
- ☐ Small Entity Status Form
- ☐ Other

Docket No.Strom.7342

UNITED STATES PATENT APPLICATION

of

AZAD AL-NAJJAR

for

ARTIFICIAL HEART

TITLE
ARTIFICIAL HEART

DESCRIPTION

Technical field

The present invention relates to an artificial heart comprising a series of towing and pressing means and intended to be implanted in a patient to replace the pumping acitivity of a heart.

The object of the present invention is to obtain an artificial heart to be implanted into a patient to replace whole of or part of the activity of a heart.

Background of the invention

The last years there has been an increased demand within cardiology for an efficient heart prosthesis.

Heart diseases and often in combination with circulatory diseases give raise to a serious threat against the patient's life.

Heart failure, as a result of a longterm weakness of the function of the heart, is a very serious condition and will sooner or later lead to death.

Access to healthy donator hearts is also very restricted and a patient may have to wait for several years for a suitable heart to be presented for implantation.

For these reasons it is of great importance to find and develop an artificial heart or rather an apparatus which can offer a continuous, harmless, comfortable, and reliable substitute for a weak, failing heart.

For many years a number of artificial heart prosthesis have been introduced. However, these show a number of deficiencies and drawbacks, such as lack of impantability, lack of physiological pliability, lack of longterm use as well as lack of pliability with regard to beat-volume.

US-A-5,139,517 shows an artificial heart which is hydraulically operated by activation from a pacemaker.

US-A-5,135,539 shows a heart prosthesis working with an electromechanical device in the form of a hydraulic micropump.

FR-A-2,710,847 shows an artificial heart having two different sacks and being operated by hydraulic oil.

US-A-4,809,676 shows a device to be implanted around aorta and which is controlled by a series of electro-magnets placed opposite each other. When the electro-magnets are activated aorta will be compressed between these so that a pumping movement is obtained.

WO 99/55399 shows an electro-magnetically controlled heart assistance technology where a number of electro-magnets are placed on the outside of the living heart, which means that one has an electro-magnetically supported heart.

US-A-6,099,460 shows an artificial heart having flexible outer walls which are influenced by electro-magnets, partly applied on the outer walls of the flexible walls, partly applied on the inside of the heart.

US-A-6,123,724 shows a construction to influence a heart by means of electro-magnetic coils attached to the ribs and permanent magnets placed adjacent the electro-magnetic coils. It is hereby a matter of supporting function when the normal pacing of a heart does not function.

US-A-6,197,055 relates to a single chamber prosthesis having a movable wall which obtains pumping by being turned from one side to the other.

US-A-5,383,840 relates to a heart supporting construction having a compression pad to surround a common heart by means of which compression pad the pumping of the heart is obtained.

None of these references discloses a rigid-wall provided prosthesis having a inner flexible compartments.

Description of the present invention

It has now surprisingly been shown possible to be able to solvet hese abovementioned deficiences by means of the present invention, which is characterized in that it comprises at least two compartments, substantially surrounded by rigid-wall provided house containing a number of electro-magnets, which are partly fixedly attached to said rigid-wall provided house, partly fixedly attached to a flexible, elastic wall layer arranged in the respective compartment, whereby the electro-magnets are arranged to draw said elqastic wall layer towards said rigid-wall provided house for filling said compartments.

The present invention will now be described more in detail in the following with reference to the accompanying drawing, wherein

FIG. 1 shows a first embodiment of the present invention in a ventricular systole phase;

FIG. 2 shows the embodiment of FIG. 1 in an atrial systole phase;
FIG. 3 shows an electro-magnet, drawing, used in the present invention in a drawing, activated position;
FIG. 4 shows an electro-magnet, drawing, in accordance with FIG. 3 in a non-drawing, inactivated position;
FIG. 5 shows an implanted heart prosthesis according to the invention with a control unit;
FIG. 6 shows a second embodiment of the invention comprising a further whole prosthesis in a diastole phase;
FIG. 7 shows the embodiment of FIG. 6 in a systole phase;
FIG. 8 shows the embodiment of FIG. 6 and 7 in a cross-section;
FIG. 9 shows a second electro-magnet, pressing, used in the second embodiment of the present invention according to FIG. 6 in an inactivated position;
FIG. 10 shows the electro-magnet according to claim 9 in a pressing, activated position;
FIG. 11 shows the embodiment of FIG. 6-8 in diastole phase (A), atrial systole phase (B) and ventricular systole phase (C);
FIG. 12 shows the embodiment according to FIG. 1-2 in diastole phase (A), atrial systole phase (B) and ventricular systole phase (C);
FIG. 13 shows generally an AV-plane of a heart and its function in one position;
FIG. 14 shows the embodiment of FIG. 13 in a second position;
FIG. 15 shows a partial prosthesis where the atrium of the former heart remains;
FIG. 16 shows a further embodiment using a divisible prosthesis; and
FIG. 17 shows a further embodiment of a partial prosthesis.

The actual function of the present invention is clearly apparent from the figures shown, as well as from the following disclosure of the natural circulation system.

The heart is surrounded by the heart sac, the pericardium, whereby the heart contains four cavities, right atrium, right ventricle, left atrium and left ventricle. The atriums are divided by the thin walled atrial septum, while the ventricles are separated by a thick walled ventricular septum. In the right atrium the two vena cavas, vena cava superior och vena cava inferior, end. From the right atrium the blood flows through the tricuspidalisostium with its valve equipment (valvula tricuspidalis) to the right ventricle from where it is then pumped via the pulmonalisostium and its valves (valvula pulmonalis) to the pulmonary artery (arteria pulmonalis).

The oxygenated blood from the lungs flows via the four pulmonary veins (venae pulmonalis) to the left atrium and then further to the left ventricle through the mitralis valve (valvula mitralis). The left ventricle is ellipsoidal in shape and not so trabecular as the right ventricle. Its myocardium, mucle wall, is 3-5 times thicker than the one of the right ventricle, which is due to the higher pressure work carried out in the left ventricle. It should be noted that the

left ventricle is dorsally placed, while the right ventricle is ventrally placed. From the left ventricle the blood is pumped out into the large body artery, the aorta.

The task of the heart is keep the blood circulating in the body. From a physiological point of view, it consists of two pumps connected in series, the right heart and the left heart. The atriums operate as reservoirs to the ventricles and facilitate a rapid filling of these during the filling phase of the heart, diastole. During the ejection phase, systole, the blood is driven with a high speed out into the aorta and arteria pulmonalis.

During rest the heart pumps 4-5 litres per minute. The blood pressure in the right ventricle during systolic phase is 15-30 mm Hg while it is 120-150 mm Hg during systolic phase in the left ventricle.

The heart cycle is normally divided into two phases, diatole – the filling of the ventricles – and systole – the emptying of the ventricles. Diastole, in turn, can be divided into three parts, viz. a first third part, a second third part and a last third part, whereby the atriums during the last third part are contracted (atrial systole).

Phase 1 diastole			Phase 2 systole
First third partI Rapid filling	Second third part	Last third part Atrial contraction	Contraction of the ventricles

In the present description the heart cycle is divided into three phases to be able to compare the natural cycle with cycle/function of the artificial heart. Hereby the three phases are diastole, atrial systole and ventricular systole

Phase 1 diastole	Phase 2 atrial systole	Phase 3 ventricular systole

The three phases of the heart rhythm are:
Diastole: During the first phase of the heart rythm, diastole, the heaert is filled with blood, and during the greater part of diastole the blood flows in the atriums and through the valves between the atriums and the ventricles.

Atrial systole: The subsequent phase is called atrial systole when the atriums contract so that the remaining blood is pressed into the ventricles.

Ventricular systole: At the end of the atrial systole and after a short delay the ventriles start to contract, whereby the pressure therein is higher than in the atriums, and the valves between the atriums and the ventricles are closed and the blood is forced out of the heart in into the pulmonary artery, *arteria pulmonalis*, and into the large body artery, *aorta*.

The natural heart contraction is released by electrical signals (action potentials) which derive from the sinoatrial bundle, which is a small collection of cells, which depolarize themselves so that action potentials are released. The sinoatrial bundle is present in the right atrium adjacent the mouth of *vena cava superior*. When action potentials have been created in the sinoatrial bundle, these will spread through the whole heart in a system of specialized muscle cells which lead these impulses through the heart and release a contraction. The sinoatrial bundle is thereby the natural pace-maker of the heart (frequency determinator). Generally, the sinoatrial bundle provides 60-70 impulses per minute.

The most known idea concerning pumping of blood from the heart has been what is called Asqueezing motion®, i.e., one has regarded the pumping e.g., from the left ventricle as a contraction of the volume of the ventricle by a contraction of the walls of the ventricle. This hypothesis has now, however, been modified.

In 1932 Hamilton & Rompf proved the importance of the long axis contraction of the left ventricle. Their principle of the pumping of the heart has then formed the basis for a larger research work during the later years.

From animal experiments one has thus drawn the conclusions that:

- the heart maintains a constant volume during both the diastole and the systole phases;
- the main pumping function of the heart depends on a caudocephaladic movement of the atrioventricular plane (54 i fig. 13, 14). This movement in turn provides a reciprocal effect of two compartments so that the atriums are filled during the systole phase of the ventricles and that the ventricles are filled at a simultaneous reduction of the volumes of the atriums in diastole phase.
- The atrioventricular plane moves towards the tip of the heart, apex, during systole while the tip of the heart moves inconsiderably during systole and diastole (about 1 mm).

Hoffman and Ritman (1985) carried out a study on dogs and arrived to the fact that the tip of the heart, apex, is maintained rather stable while the atrioventruclar plane moves towards apex during systole and towards the atriums during diastole, when the atriums and the ventricles are are emptied and filled, alternativeiy.

Hamilton and Rompf draw their conclusion from animal experiments, but so did also Hoffman and Ritman. But the systolic shortening of the longitudinal axis of the ventricles, i.e., the down going movement of the base of the heart towards apex during systole has been studied on humans using different techniques.

The most extensive studies with regard hereto during the last years have been carried out by Lundbäck (1986). He proved the model of ventricular pumping, the same as previously presented by Hamilton and Rompf, and Hoffman and Ritman, respectively. These studies prove the importance of a longitudinal axis contraction and the systolic movement of the atrioventrcular plane towards apex, and that the heart, simultaneously herewith, maintains a constant volume during both diatole and systole, thanks to the heart sac, the pericardium, and the support from surrounding tissues., (Wandt, Birger, Mitral Ring Motion in Assessment of Left Ventricular Function, Linköping 1998).

During early diastole phase, fig. 14, the atrioventricular plane (the AV-plane) moves with its prosthesis valves in the heart rapidly upward towards the atriums. At the end of the diastole phase the AV-plane moves still more as a result of the contraction which occurs in the atriums. In his study of the left ventricle, Lundbäck has noticed that the left ventricle has an outer diameter of about 68 mm in a healthy young person. In this way the left ventricle contracts during systolic phase in a substantially cylindrical segment having a length of 19 to 22 mm (longitudinally) and having a radius of about 34 mm. The cylindrical segment has a volume of 69 to 80 ml which value corresponds with the normal value of the stroke volume of a healthy young person, i.e., the stroke volume is determined by the longitudinal movement of the AV-plane as well as of its surface in the left ventricle. (Wandt, Birger, Mitral Ring Motion in Assessment of Left Ventricular Function, Linköping 1998).

The present invention is a heart prosthesis which substantially eliminates or prevents the drawbacks and problem, which are connected with prior invented and evaluated heart prosthesis.

Fig. 1, 2, 6, 7, 8, 11, 12 show the present invention in its entirety, while fig. 3, 4, 5, 9, 10, show certain details of an embodiment of the invention, fig. 13, 14 show, generally an AV-plane in a heart and its function according to Hoffman and Ritman-s, Hamilton and Rompf-s, and Lundbäck-s hypothesis of heart physiology.

The present invention is a completely implantable heart prosthesis which replaces the natural heart, completely or partly. The outer wall 2 of the prosthesis is created of a rigid, or semi-rigid material, such as a biocompatible polymer and is with regard to size and form about proportional to the natural heart. The outer layer 3 of the walls being in contact with

body tissues is construed of a biocompatible thermoplastic material.

The prosthesis consists of two ventricles each being provided with two openings equipped with artifical valves 4. Through one of the openings blood is pumped out and through the other one blood is received. Further, there are two further compartments, comparable to the natural atriums, whereby the right atrium 5 of the prosthesis is provided with three openings. Off these, is one an opening for outgoing blood to the right ventricle 12 of the prosthesis, and two are inlet openings for blood into the atrium 5. Left atrium 6 comprises however, five openings, of which one is an outlet opening for blood to the left ventricle 13 and the other four are inlet openings through which blood passes from the two lungs to left atrium.

Each compartment of the four described above are provided with their separate activation and controlling device. This device is made of a flexible layer (wall) 7 of an elastic, biocompatible material which is utilized for pumping of blood. This layer 7 is fixed to the respective opening 8. The innermost layer 1 of this first mentioned layer 7 is in direct contact with the flowing blood and is construed of a hemocompatible material, whereby simulataneously a blood receiving compartment is formed. A free distance 9 is present between the inner side of the outer rigid wall 2 of the prosthesis and the said flexible layer 7.

To summarize, the artificial heart contains four compartments: one corresponding to right atrium 5, one which corresponds to right ventricle 12, one which corresponds to left atrium 6, and one which corresponds to left ventricle 13. In the right atrium of the prosthesis the two vena cava end, vena cava superior 14 and vena cava inferior 15. The rigid outer wall 7 of the prosthesis corresponds to the pericardium of the natural heart, while the flexible, elastic layer 7 surrounding the four compartments corresponds to the natural muscle walls, the myocardium, of the ventricles and the atriums.

From the right atrium 5 of the prosthesis blood flows through a prosthetic valve 4 to the right ventricle of the prosthesis from where it is then pumped to the pulmonary artery (arteria pulmonalis) 16 via the pulmonallsostium of the prosthesis, which is provided with a prosthetic valve.

The oxygenated blood from the lungs flows via the four pulmonary veins (venae pulmonalis) 17 to the left atrium 6 of the prosthesis and then further to the left ventricle 13 of the prosthesis through a prosthetic valve. The elastic layer of the left ventricle of the prosthesis should be 3 to 4 times as thick as the elastic layer of the right ventricle which is due to the higher pressure work at the left side compared to the right side. Left ventrile pumps blood into the large body artery, aorta 18.

The task of the artificial heart is to keep the blood circulating in the body and consists, for that reason, of two pumps connected in series, in the same way as the natural heart, a right and a left pump. The two atriums of the prosthesis serve as reservoirs for the ventricles of the prosthesis and facilitates a rapid filling of these during the filling phase of the prosthesis, diastole. During the ejection phase, systole, the blood is driven with a high speed out into aorta and arteria pulmonalis.

Within the hard wall 2 there is a number of mini electro-magnets 10 (cf in particular fig. 3 and 4). The material of the outer hard wall should then be a suitable thermoplastic material. The movable part of the magnets, the core 11, 19, is present in a fixed contact with the flexible, elastic layer 7. Each magnet 10 contains further a field conduit 20 surrounding the movable metallic core 11, 19.

The elctro-magnetic system is driven from an eletrical source 21. The current can be added in different ways, such as using compact, rechargeable batteries, or via a transformer with a rectifier, which adds a direct current. A smaller electrical conduit running intracutaneous from the inside of the body to its outside is surrounded by a biocompatible material, e.g., Dacron®. Alternatively, the power supply may carried out through transcutaneous transfer of electrical energy through the skin to specific electrodes underneath the skin, in which way the need for using an intra cutaneous running conduit will be eliminated.

The artificial heart functions according to the following.
The function of the artificial heart can be separated into three phases, in the same way as the function of the natural heart, as described above.

Diastole: During the diastole phase the elastic layer of the respective ventricle is contracted under influence of the electro-magnets (drawing magnets) in a direction towards the rigid outer walls (fig. 12A). Hereby the artificial heart is filled with blood. During the major part of diastole blood flows into the atriums and througfh the valves between atriums and ventricles.

Atrial systole: During this phase the effect of the electro-magnets (drawing magnets) on the elastic layer in the respective atrium (fig. 12B), whereby the elastic layer is resiliently returned so that remaining amount of blood in the respective atrium is pressed into the ventricles.

Ventricular systole: During this phase the effect of the electro-magnets on the elastic layer in the respective ventricle ceases (fig. 12C). Hereby, the elastic layer returns so that blood is forced out of the ventricles and into the pulmonary artery and aorta. Simultaneously, during this phase the elastic layer in the respective atrium is drawn (fig. 12C) by means of

the electro-magnets (drawing magnets) towards their outer rigid wall.

The pressure which is created in the respective ventricle is commonly about 100 to 120 mm Hg on the left side and 15 to 30 mm Hg on the right side. The pressure is separately controlled in the four respective compartments by means of the electro-magnets and by means of the thickness of the elastic walls (the thicker the wall, the higher the pressure). The number of electro-magnets connected to the respective compartment may also be varied depending on the thickness of the elastic layer and on the drawing-pressing-ability, as desired.

The core of the electro-magnets (the movable metallic core) is drawn out of the field conduit by means of the effect of the elastic layer (fig. 3). A conduit from the electro-magnets runs to a digital, electronic circuit board 22, the electronics of which is similar to previously known Acardiac pacing system® in pace-makers, and which regulates the frequency of the electrical impulses to the electro-magnetic system in the prosthesis/artificial heart.

Said digital electronic circuit board 22 produces and regulates pulses of electrical current to and through the electro-magnets, whereby a magnetic field is created which leads to that the metallic core is drawn into the field condit (fig. 4). This in turn leads to that the elastic layer is drawn towards the rigid outer wall.

The digital circuit board 22 receives an input signal from an electrode or sensor 23 which is placed in or adjacent the sinoatrial bundle to receive the natural electrical impulses (one may save that part of the right atrium comprising the sinoatrial bundle at a surgical extraction of the failing heart at the implantation of the prosthesis). Alternatively, one may use a blood pressure sensor 24 placed in the wall of the left arteria carotis communis. This sensor is sensitive to a variation of the blood pressure in arteria carotis communis. In this way the frequency of the impulses derived from the digital electronic circuit board to the electro-magnets, is controlled. Thereby, the prosthesis answers to an increase or decrease to the natural, physiological demand of the body.

The circuit board can be programmed so that the electro-magnets of the respective atrium and ventricle are separately activated. Furthermore, the size of the current activating the electro-magnets of the respective atrium and ventricle can be regulated each individually by providing a desired degree of drawing of the elastic layer towards the rigid outer wall.

An alternative embodiment of the present invention is by implanting only one two-compartment unit, e.g., only right and left ventricles. The two ventricles have, in such a case, the same criteria as described above. They are sutured to the natural respective atrium of the patient, whereby the valves between atriums and ventricles are present in the

prosthesis part. Hereby, the upper part of the heart prosthesis in such a way that there is only one ingoing opening on each side, one on the right side and one on theleft side. The ingoing openings are sewn up with the remaining natural atriums (left and rright side). This technique helps in contributing to a faster, easier and more safe surgical technology (cf fig. 15)

In order to further improve the prosthesis the upper outer walls of the atriums can be construed in such a way that it consists of two, almost identical parts, which together forms the outer rigid wall of the atriums (cf fig. 16). Herein the parts has been denoted A and B. Part A is sewn up with the natural atrium and part B will be in a fixed relation to the remaining part of the pump/prosthesis. This technique facilitates optional future reoperations, if one should need to replace the whole or part of the prosthesis. One can replace damaged parts or the aprts one count on should need to be replaced after a certain time period, without need for removing part A, which is fixedly connected to the atrium. The only thing one needs to do is to screw loose part B from part A and remove the prosthesis including part B.

In accordance with another embodiment half of, or only a quarter of a heart be replaced using a prosthesis according to the present invention. Such a half prosthesis is shown in fig. 17. Two such half prosthesis may also form a total prosthesis.

A further embodiment of the invention is shown in fig. 6 and 7, which embodiment also is a completely implantable prosthesis, whereby it consists of two halves (right and left) where each half is divided into two compartments, corresponding to an atrium 25, 26 and one ventricle 27, 28. These compartments are connected with each other via a valve prosthesis 29, 40. The walls of the atriums and ventricles consist, as described above, of an elastic, flexible layer 30. Furthermore, there is an outer rigid wall 31, such as in the previously described embodiment, but contrary to that there is a slit 32 between the outer walls of the ventricles and the outer walls of the atriums. This slit is 10 to 20 mm. The walls of the atriums, the elastic wall, is fixed at the base of this prosthesis to the outer walls 33 of the atriums, simulataneously as the elastic walls of the ventricles are fixed to the outer walls of the ventricles in the apex of the prosthesis or its tip (lower end) 34.

Further there are a number of metal pins 35 having a diameter of one to some millimetres and having a length of 3 to 4 cm arranged to hold the outer walls of the atriums and the outer walls of the ventricles in fixed relation to each other. A thin layer 36 of the outer rigid wall covers the slit described on the outside of the prosthesis.

Further, there is a metallic plate 37 which corresponds to the atrioventricular plane 54 of the natural heart (fig. 13, 14), which plate has a thickness of one to some millimetres and

separates the atriums 25, 26 from the ventricles 27, 28. The elastic wall layer of the atriums is fixedly arranged to the upper side 38 of the metal plate 37 and the elastic wall layer of the ventricles is fixedly arranged to the lower side of the metal plate 37. The metal plate 37 can be exchanged to any other suitable material, which fulfils the demands of being long term lasting and feasibly non-elastic or flexible.

In the metal plate 37 there are two openings connecting the atriums 25, 26 of the prosthesis with the ventricles 27, 28 of the prosthesis with each other, one in each side. Theopenings correspond to the litralis valve29 and the tricuspidalis valve 40 and are each provided with vale prosthesis. Simultaneously, each ventricle has an outlet opening which is provided with valve prosthesis and which correspond to pulmonalis valve 41 on the right side, and the aorta valve 42 on the left side and which are arranged outside the metal plate 37 (fig. 8).

In the same way as in the above described embodiment this embodiment comprises four compartments: one 26 corresponding to the right atrium, one 28 corresponding to the right ventricle, one 25 corresponding to the left atrium and one 27 corresponding to the left ventricle. In the right atrium 26 of the prosthesis the two vena cavas end, vena cava superior 43 och vena cava inferior 44.

From the right atrium 26 blood flows through the valve prosthesis 40 to the right ventricle 28 of the prosthesis from whyere it is then, via the pulmonalisostium of the prosthesis being provided with a valve prosthesis 41 is pumped to the pulmonary artery (arteria pulmonalis) 45.

The oxygenated blood from the lungs flows via the four pulmonary veins (venae pulmonalis) 46 to the left atrium of the prosthesis and then further to the left ventricle 27 of the prosthesis through a valve prosthesis 29. The elastic layer of the left ventricle of the prosthesis should be 3-4 times thicker than that of the right ventricle, which is due to the larger pressure work carried out on the left side compared to the right side. Left ventricle pumps blood into the large body artery, aorta 47.

The task of the artificial heart is to keep blood circulating in the body and consists, for that reason, of two pumps connected in series, in the same way as the natural heart, one right and one left pump. The two atriums of the prosthesis serve as reservoirs for the ventricles of the prosthesis and facilitates a rapid filöling of these during the filling phase, diastole, of the prosthesis. During the ejection phase, systole, the blood is driven with a high speed out into aorta and arteria pulmonalis.

The outer rigid wall 31 of the prosthesis, in which the metal plate 31 of the prosthesis

moves to and fro, it corresponds to the surrounding sac, the pericardium, of the natural heart. In the same way the elastic wall 30 of the prosthesis corrsponds to the muscle wall, the myocardium, of the natural wall. As described above, the to and fro going movement of the metal plate within the slit 32 of the outer rigid wall of the prosthesis is similar to the movgement of the AV-plane of the natural heart according to the models of Hamilton and Rompf (1932), Hoffman and Ritman (1985) and Lundbäck (1986).

Unlike the first described embodiment, this embodiment shows some electro-magnets 48 (fig. 9 and 10) having an opposite function (pressing magnets) which are arranged to the upper edge (fig. 8) in the outer wall of the ventricles. The movable core 49 of the electro-magnets are fixed to the underside 39 of the metal plate. Further, there is a number of electro-magnets 50 (fig. 3 and 4) within each outer wall of the ventricles. The movable parts of these electro-magnets (drawing magnets) are present and fixed to the outside of the elastic wasll layer 30 of the ventricles.

In stead of pressing magnets placed outside of the ventricles in the rigid wall, drawing magnets can be placed outside the atriums in the upper edge of the rigid wall. Even combinations of drawing and pressing electro-magnets can be present.

Further, there is a number of electro-magnets 51 (drawing) in the outer wall of each atrium, the cores of which are fixedly arranged to the elastic wall layer 30 of the atriums.

The material of the outer wall 30 of the heart prosthesis should, as mentioned above, be made of a suitable, biocompatible thermo plastic material. Further, the elastic wall should as such or in a laminate has an Ahemokompatibel® surface directed to the respective compartment, which surface will be brought into cotact with blood.

Each electro-magnet of the type pressing magnet comprises a field conduit 52 surrounding the core 49. When the electro-magnets are arranged as pressing magnets the core is pressed into the field conduit by means metal plate by means the effect of the thick, elastic wall layer 30 of the ventriles (fig. 9), whereby they are prosthesissed out of the field conduit when current is allowed to pass through this (fig. 10). A conduit from the electro-magnets runs to a digital, electronic board 22, which corresponds to the board 22, fig. 5, of the embodiment first described.

The prosthesis can be driven in the same way as the first described embodiment.

This further embodiment functions as follows:
Diastole: In the beginning of diastole (fig. 11A) the metalplate is drawn up towards the lower edge of the outer wall of the atrium of the prosthesis by means of electro-magnets

(pressing) 48 and the elastic wall of the respective ventricle is drawn towards its hard rigid wall by means of the electoi-magnet 50 (drawing). During the first third part to the first half of the diastole phase of the prosthesis the filling of the ventricle is done very fast due to the blood collected in the atriums during the previous systole phase of the ventricles, and which is now pressed to the respective ventricle through valve prosthesis, which correspond to the mitralis 29 and tricuspidalis 40 valves, when trhe metal plate 37 is pushed upward towards the atriums by means of the magnetic force. Simultaneously, there is a reduction of the volumes of the atriums of the prosthesis, as the heart maintains a constant volume during both diatole and systole phases (acc. to Hoffman & Ritman, Hamilton et al, Lundbäck a.o.). Alternatively the metal plate 37 of the prosthesis can be pressed upward towards the atriums of the prosthesis in the beginning of the diatole phase by means of a hydraulic device being activated by means of an implanted mini hydraulic engine.

During the second third of the diatole a minor amount of blood is moved directly from the veins through the atriums to the ventricles.

Atrium systole: During the first phase (fig. 11B) the drawing effect of the electro-magnets 51 on the elastic wall layers of the respective atriums cease, whereby the elastic wall layers retains to a basic position, whereby the remaining part of the blood of the respective atrium is pressed into the respective ventricle.

Ventricle systole: During this phase (fig. 11C) the effect of the electro-magnets 50 in the outer rigid wall of the ventricles, ceases, whereby the elastic layer retains its basic position and the metal plate 37 is drawn to the ventriles (the apex of the prosthesis) by means of the effect by the thick elastic inner wall layers of the ventricles, and after ceased pressure influence of the pressing magnets 48. The inner wall layer hereby is resillently returned and the blood is pressed out through the pulmonary artery 45 and aorta 47, when the valve prosthesis corresponding to the mitralis och tricupidalis valves have been closed. When the atrium systole phase of the atrium is finished the elastic wall layer of the atriums is drawn towards the outer hard rigid walls by means of the electro-magnets 51 present in the outer rigid walls of the atriums, whereby the pressure decreases in the respective atrium and the blood flows into the respective atrium of the prosthesis from the veins, vena cava superior, och vena cava inferior, and the pulmonary vein, venae pulmonalis.

The pressure being created in the respective ventricle is commonly 100 to 140 mm Hg on the left side and 15 to 30 mm Hg on the right side. The pressure is controlled separately in the four respective compartments depending on the thickness of the elastic walls, which can be the same or not in the different respectve compartments (the greater thickness, the larger pressure)

CLAIMS

1. Heart prosthesis/artificial heart comprising a series of drawing and pressing means and intended to be implanted in a patient to replace the pumping acitivity of a heart, whereby comprises at least two compartments (5, 6, 12, 13, 25, 26, 27, 28), substantially surrounded by rigid-wall provided house (2, 3, 31) containing a number of drawing and/or pressing devices (10, 48, 50),
characterized in
that it comprises two halves, comprising an atrium (25, 26), and ventricles (27, 28) respectively, separated with a valve (29, 40) provided plate (37) which plate (37) is arranged to be able to be moved between the ventricles (27, 28) and the atriums (25, 26) by means of drawing and/or pressing devices (48, 50) arranged in said rigid wall provided house (31).

2. Heart prosthesis according to claim1,
characterized in
that it comprises four compartments (5, 6, 12, 13, and 25, 26, 27, 28, respectively).

3. Heart prosthesis according to claim1,
characterized in
that the drawing and/or pressing devices (10, 48, 50) are drawing and pressing electromechanical devices, respectively, including electro-magnets.

4. Heart prosthesis according to claim1,
characterized in
that said plate (37) is arranged to be moved by means of electro-magnets (48) or a hydraulic device arranged in said wall (31).

5. Heart prosthesis according to claim1,
characterized in
that the drawing and/or pressing devices are drawing, and pressing, respectively, hydraulically activated pistons.

6. Heart prosthesis according to claim1,
characterized in
that it is arranged to be controlled digitally via a soft-ware present in a circuit board (22) in a diastole, atrium systole, and systole phase, respectively.

7. Heart prosthesis according to claim1,
characterized in
that it is supplied with energy from one or more DC batteries.

ABSTRACT

The present invention relates to a heart prosthesis/artificial heart comprising a series of drawing and pressing means and intended to be implanted in a patient to replace the pumping activity of a heart, whereby it comprises at least two compartment, substantially surrounded by rigid-wall provided house containing a number of drawing and/or pressing devices, which are partly fixedly attached to said rigid-wall provided house, partly fixedly attached to a flexible, elastic wall layer arranged in the respective compartment, whereby the drawing and/or pressing devices are arranged to draw said elastic wall layer towards said rigid-wall provided house for filling said compartments.

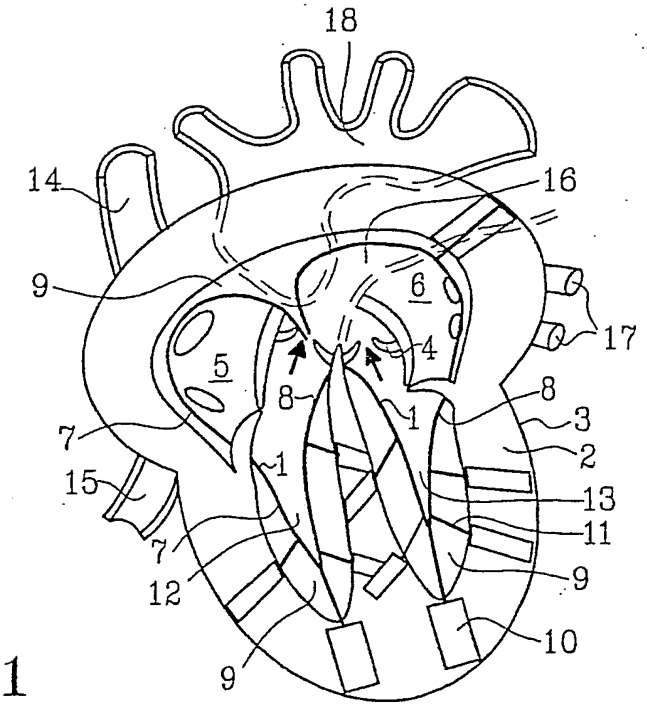
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FIG.1

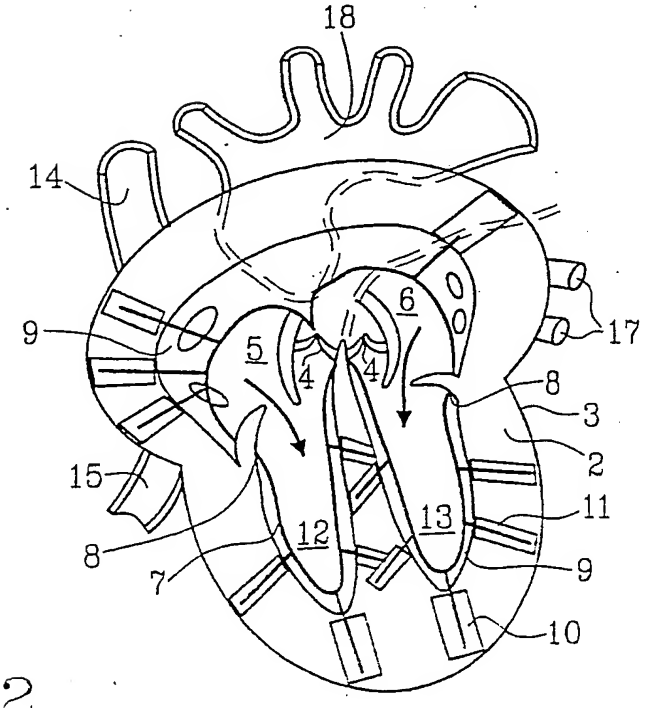
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FIG.2

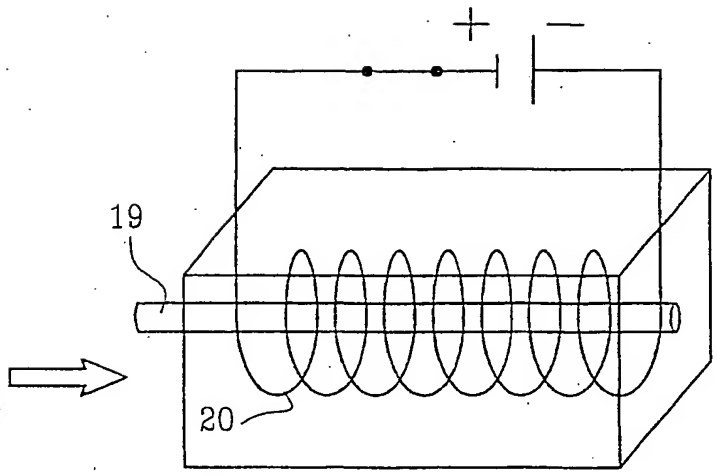


FIG.3

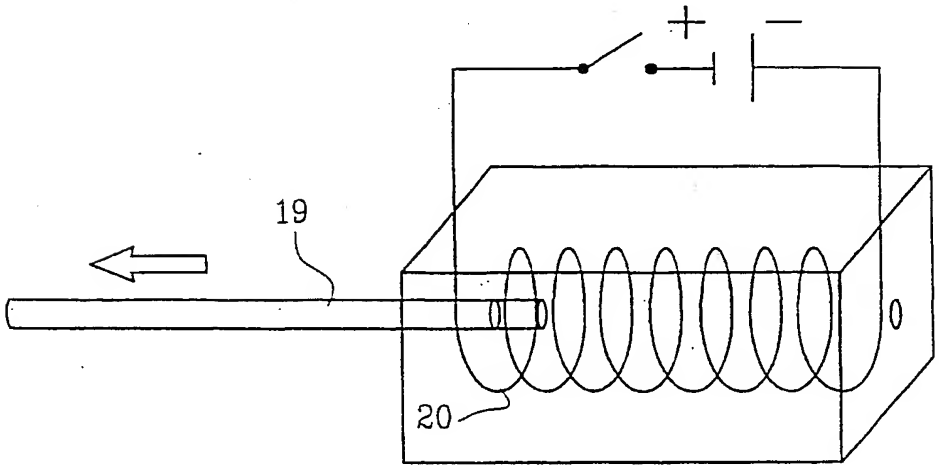
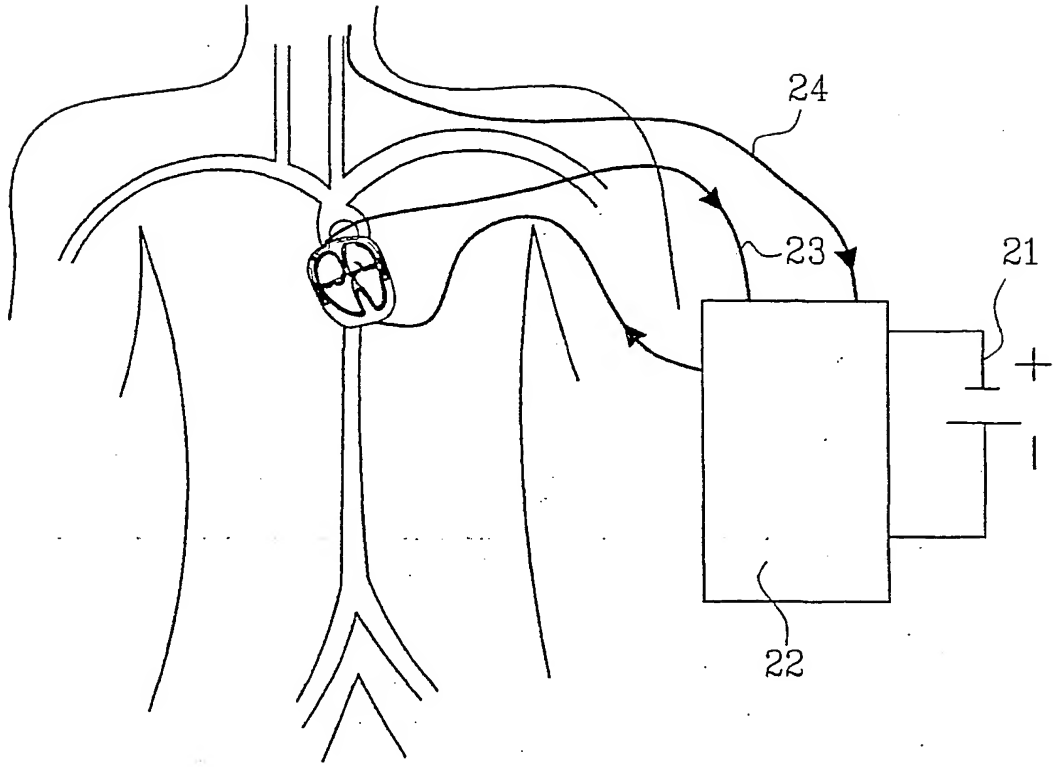


FIG.4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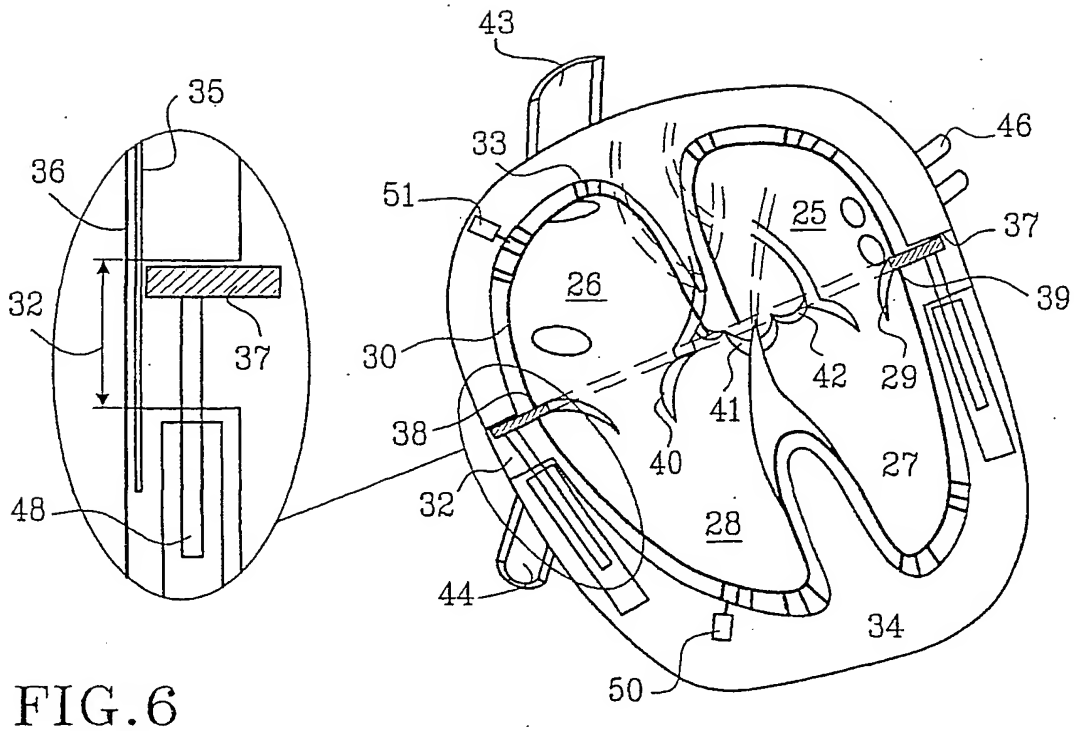
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FIG.6

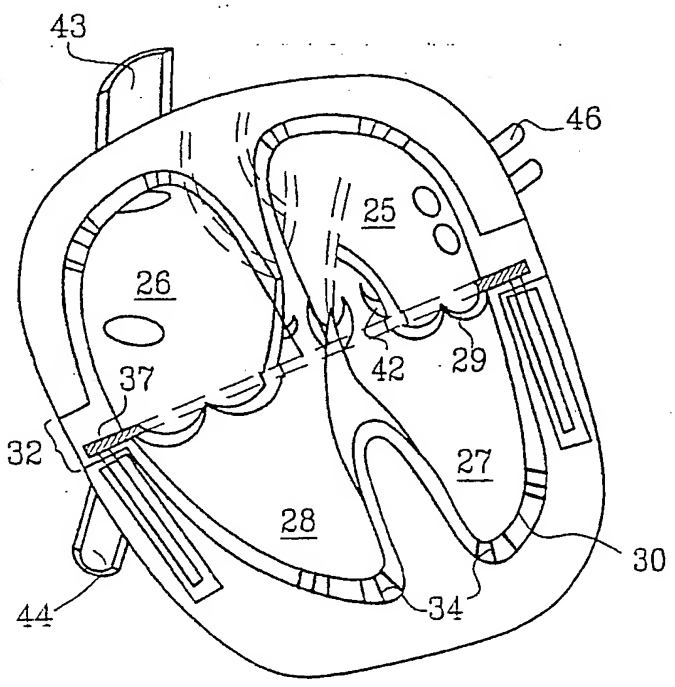
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FIG.7

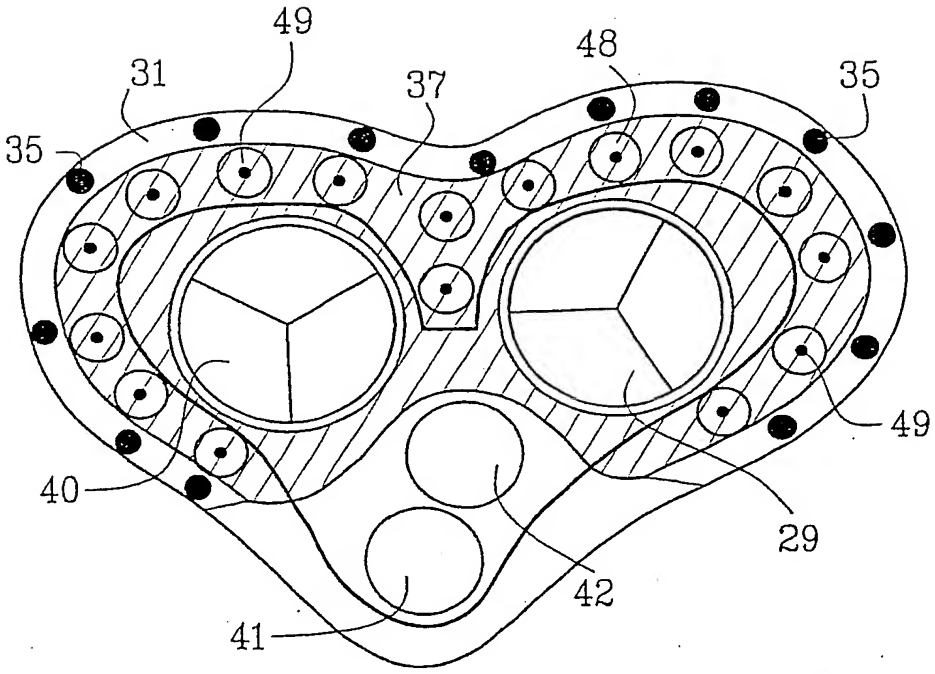

FIG.8

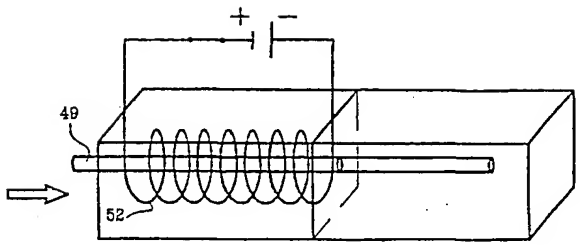

FIG.9

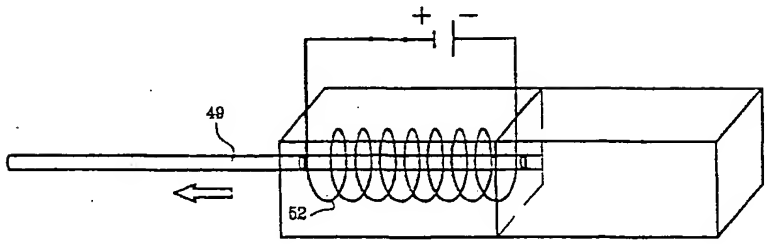

FIG.10

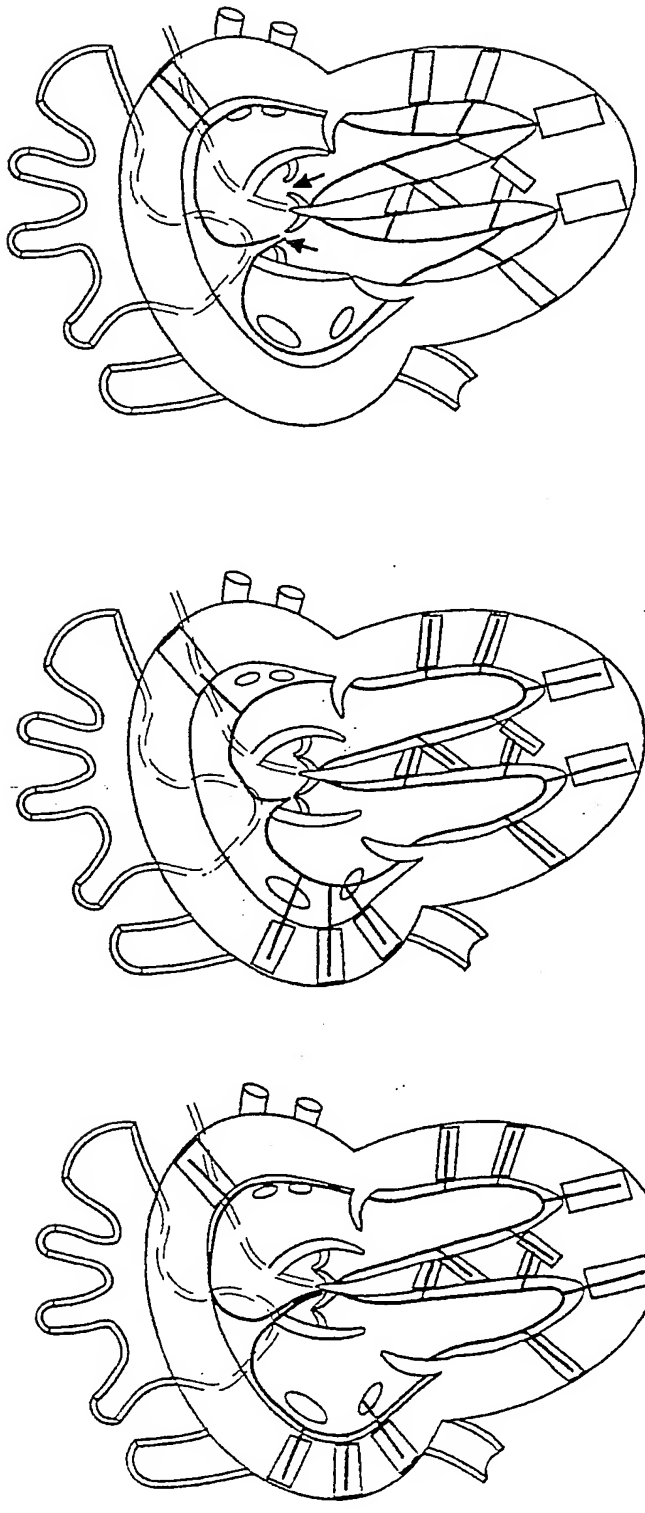

FIG.12

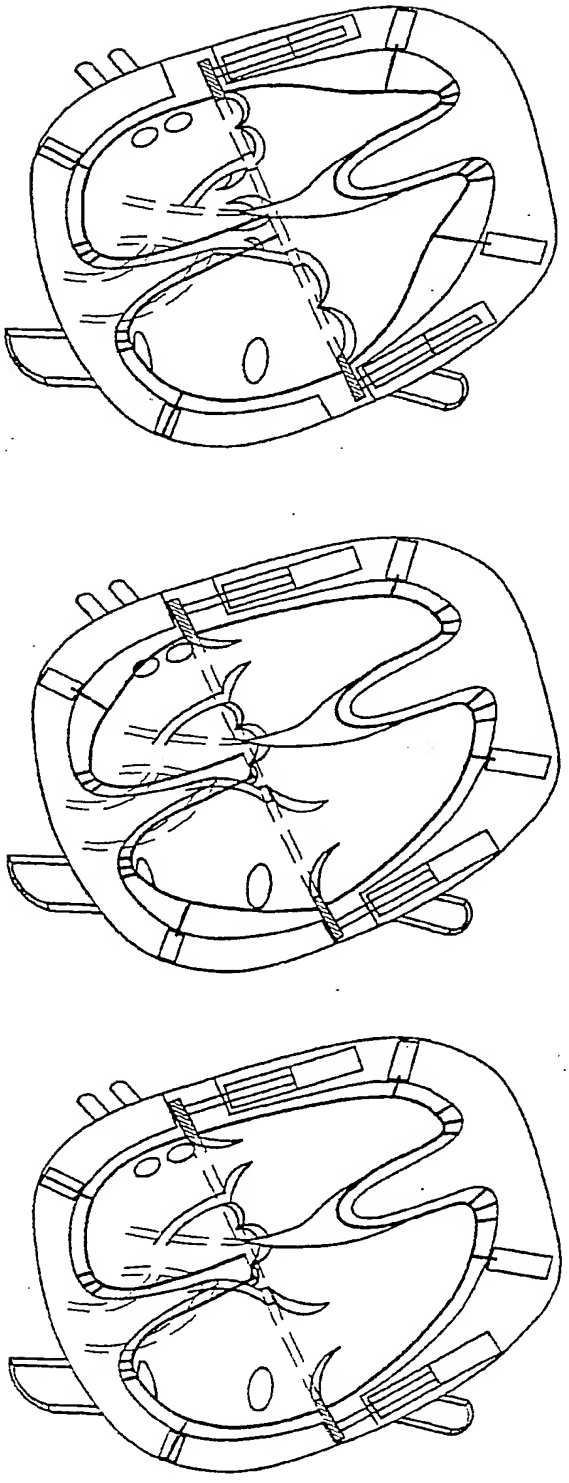

FIG.11

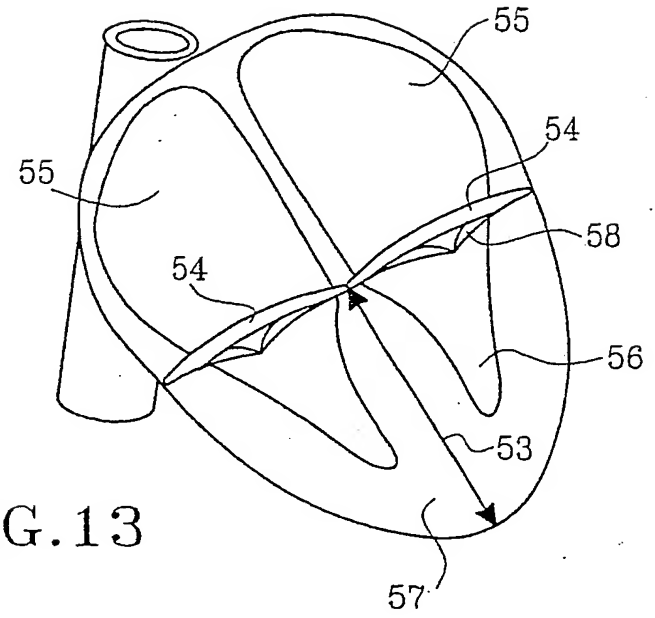

FIG.13

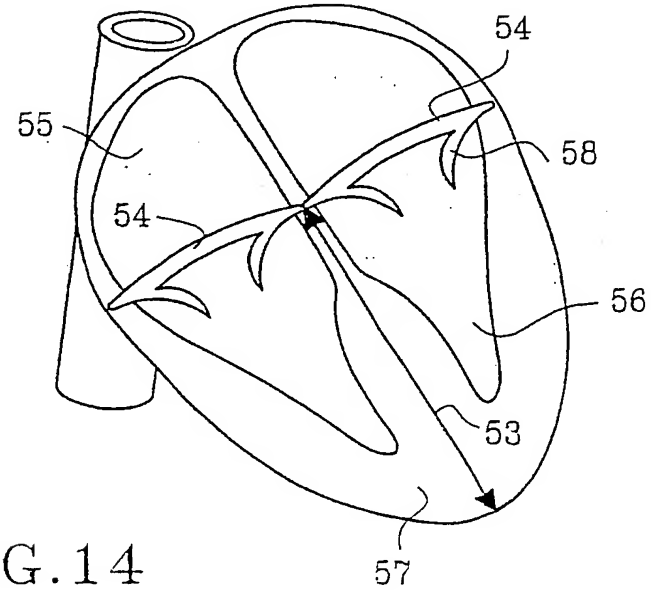

FIG.14

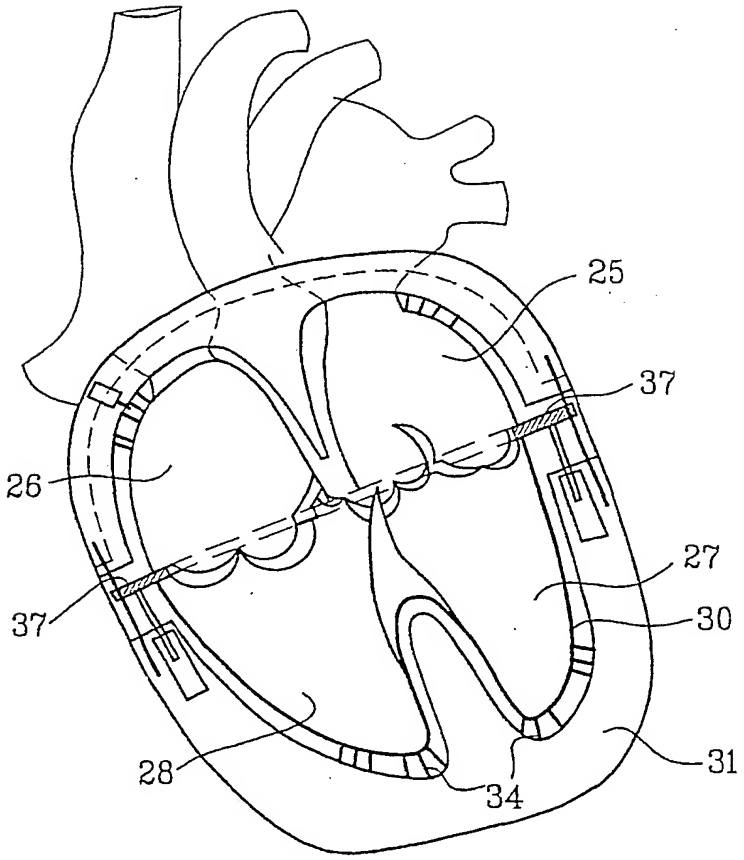

FIG.15

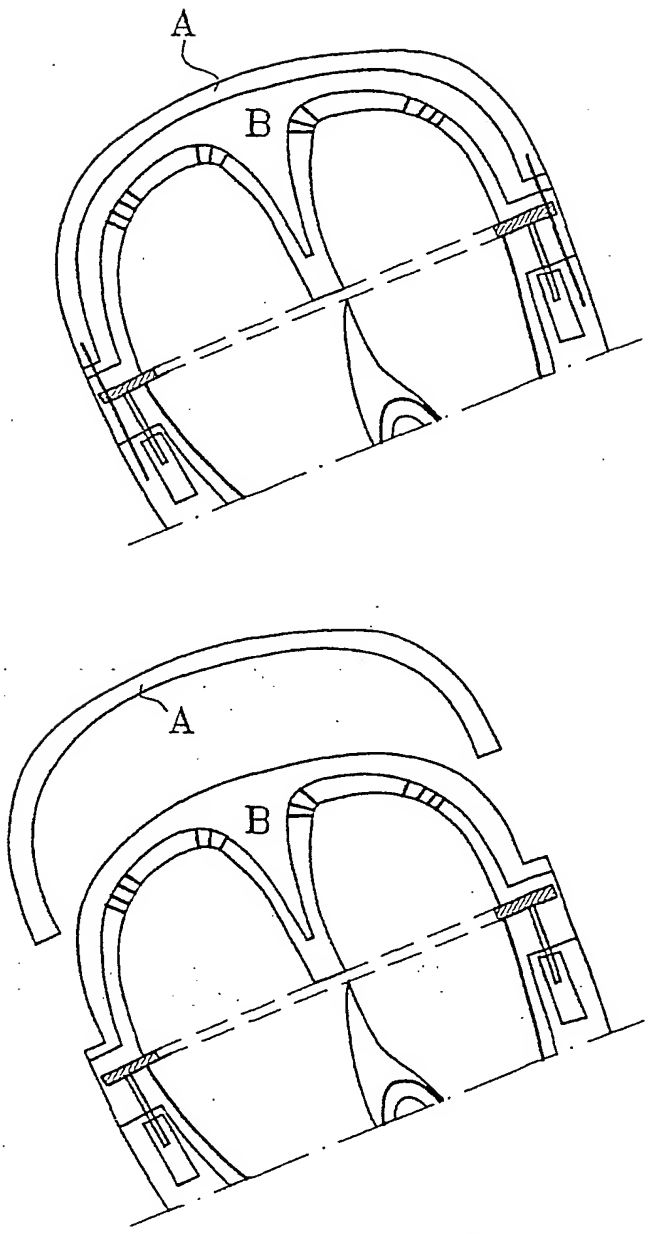

FIG. 16

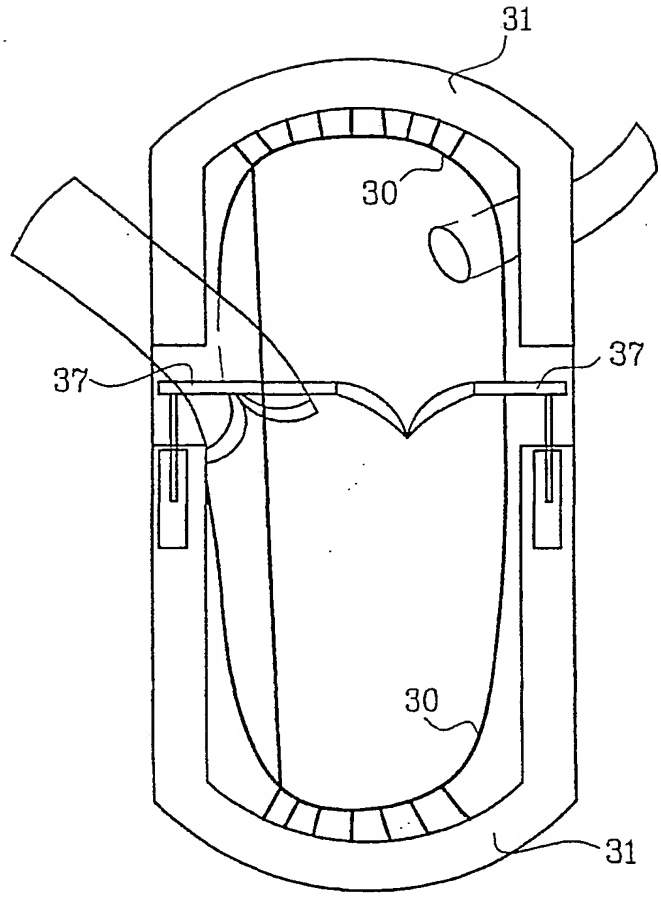

FIG. 17

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

APPLICANT:	Azad Al-Najjar	**GROUP:**	Unknown
SERIAL NO:	Unknown	**EXAMINER:**	Unknown
FILED:	Herewith		
FOR:	**ARTIFICIAL HEART**		

Mail Stop Patent Application
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

INFORMATION DISCLOSURE STATEMENT

In compliance with 37 C.F.R. §§1.56, 1.97, and 1.98, Applicant submits a copy of the foreign cited patent with an English translation of the Abstract listed on the attached Form PTO-1449.

The listed documents were recently cited in a corresponding PCT application, and a copy of the International Search Report is being submitted herewith for purposes of convenience.

The Commissioner is authorized to charge Deposit Order Account No. 19-0079 for any further fee that is required.

Respectfully submitted,

Matthew E. Connors
Registration No. 33,298
Samuels, Gauthier & Stevens, LLP
225 Franklin Street, Suite 3300
Boston, Massachusetts 02110
Telephone: (617) 426-9180
Extension: 112

CERTIFICATION UNDER 37 C.F.R. § 1.10

I hereby certify that this paper (along with any paper referred to as being attached or enclosed) is being deposited on November 12, 2003, in an envelope as "Express Mail Post Office to Addressee" Mailing Label Number EL960883183US addressed to: Mail Stop Patent Application,. Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

Deborah M. Castello

FORM PTO-1449 (Rev. 5/92) SAMUELS, GAUTHIER & STEVENS LLP 225 Franklin Street, Boston, MA 02110 Telephone: (617) 426-9180 **INFORMATION DISCLOSURE STATEMENT BY APPLICANT**	7342 ATTORNEY DOCKET Azad Al-Najjar APPLICANT: Herewith FILING DATE:	Unknown SERIAL NO. Unknown GROUP: Unknown EXAMINER:

U.S. PATENT DOCUMENTS

EXAMINER INITIAL		DOCUMENT NUMBER	DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE
	AA	5,135,539	8/4/92	Carpentier			1/11/89
	AB	6,123,724	9/26/00	Denker			
	AC	6,099,460	8/8/00	Denker			
	AD	5,139,517	8/18/92	Corral			
	AE	4,809,676	3/7/89	Freeman			
	AF						
	AG						
	AH						
	AI						

FOREIGN PATENT DOCUMENTS

EXAMINER INITIAL		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUBCLASS	TRANSLATION YES NO
	AJ	WO 95/09660	4/13/95	WIPO			Yes(Abstract)
	AK						
	AL						
	AM						

OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)

EXAMINER INITIAL		
	AM	
	AN	
	AO	

EXAMINER	DATE CONSIDERED

EXAMINER: **Initial if citation considered, whether or not citation is in conformance with MPEP 609; draw line through citati n if not in conformance and not considered. Include copy of this form with next communication to applicant.**

INTERNATIONAL SEARCH REPORT

International application No.
PCT/SE 02/00689

A. CLASSIFICATION OF SUBJECT MATTER

IPC7: A61M 1/10
According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC7: A61M

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

SE,DK,FI,NO classes as above

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 5135539 A (CARPENTIER), 4 August 1992 (04.08.92), figures 1-2, claims 1-14 --	1
X	FR 2710847 A1 (DEMANDEUR(S)), 14 April 1995 (14.04.95), figures 1,2, claims 1-5 --	1
A	US 6123724 A (DENKER), 26 Sept 2000 (26.09.00), figures 1-4, claims 1-17 --	1-8
A	US 6099460 A (DENKER), 8 August 2000 (08.08.00), figures 1-6, claims 1-31 --	1-8

[X] Further documents are listed in the continuation of Box C. [X] See patent family annex.

* Special categories of cited documents:
"A" document defining the general state of the art which is not considered to be of particular relevance
"E" earlier application or patent but published on or after the international filing date
"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
"O" document referring to an oral disclosure, use, exhibition or other means
"P" document published prior to the international filing date but later than the priority date claimed
"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
"X" document of particular relevance: the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
"Y" document of particular relevance: the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
12 June 2002	09 -07- 2002
Name and mailing address of the ISA Swedish Patent Office Box 5055, S-102 42 STOCKHOLM Facsimile No. +46 8 666 02 86	Authorized officer Agneta Änggård/SN Telephone No. +46 8 782 25 00

Form PCT/ISA/210 (second sheet) (July 1998)

INTERNATIONAL SEARCH REPORT

International application No.
PCT/SE 02/00689

C (Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US 5139517 A (CORRAL), 18 August 1992 (18.08.92), figures 1-4C, claims 1-12 --	1-8
A	US 4809676 A (FREEMAN), 7 March 1989 (07.03.89), figures 1-2, claims 1-20 -- --------	1-8

INTERNATIONAL SEARCH REPORT

Information on patent family members

01/05/02

International application No.
PCT/SE 02/00689

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
US 5135539 A	04/08/92	AT 89177 T	15/05/93
		CA 1329450 A	17/05/94
		DE 68906403 D,T	04/11/93
		DK 133489 A	10/05/89
		EP 0324669 A,B	19/07/89
		SE 0324669 T3	
		ES 2042015 T	01/12/93
		FR 2625903 A,B	21/07/89
		JP 2005966 A	10/01/90
FR 2710847 A1	14/04/95	WO 9509660 A	13/04/95
US 6123724 A	26/09/00	AU 4229700 A	14/11/00
		EP 1169086 A	09/01/02
		WO 0061227 A	19/10/00
US 6099460 A	08/08/00	AU 3570199 A	16/11/99
		CA 2329766 A	04/11/99
		EP 1075290 A	14/02/01
		US 6309341 B	30/10/01
		WO 9955399 A	04/11/99
US 5139517 A	18/08/92	NONE	
US 4809676 A	07/03/89	NONE	

PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference	FOR FURTHER ACTION	See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)
P16203PC00/CA		
International application No.	International filing date *(day/month/year)*	Priority date *(day/month/year)*
PCT/SE02/00689	08.04.2002	10.04.2001
International Patent Classification (IPC) or national classification and IPC		
A61M 1/10		
Applicant		
AL-NAJJAR, Azad		

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.

2. This REPORT consists of a total of 3 sheets, including this cover sheet.

   ☒ This report is also accompanied by ANNEXES, i.e., sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

   These annexes consist of a total of 1 sheets.

3. This report contains indications relating to the following items:

   - I ☒ Basis of the report
   - II ☐ Priority
   - III ☐ Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
   - IV ☐ Lack of unity of invention
   - V ☒ Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
   - VI ☐ Certain documents cited
   - VII ☐ Certain defects in the international application
   - VIII ☐ Certain observations on the international application

Date of submission of the demand	Date of completion of this report
11.11.2002	16.06.2003
Name and mailing address of the IPEA/SE	Authorized officer
Patent- och registreringsverket Box 5055 S-102 42 STOCKHOLM Facsimile No. 08-667 72 88 Telex 17978 PATOREG-S	Agneta Änggård/ES Telephone No. 08-782 25 00

Form PCT/IPEA/409 (cover sheet) (January 1998)

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.
PCT/SE02/00689

I. Basis of the report

1. With regard to the **elements** of the international application:*

☐ the international application as originally filed

☒ the description:
pages 1-13 , as originally filed
pages _____ , filed with the demand
pages _____ , filed with the letter of _____

☒ the claims:
pages _____ , as originally filed
pages _____ , as amended (together with any statement) under article 19
pages _____ , filed with the demand
pages 14 , filed with the letter of 09.05.2003

☒ the drawings:
pages 1-12 , as originally filed
pages _____ , filed with the demand
pages _____ , filed with the letter of _____

☐ the sequence listing part of the description:
pages _____ , as originally filed
pages _____ , filed with the demand
pages _____ , filed with the letter of _____

2. With regard to the **language**, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.
These elements were available or furnished to this Authority in the following language _____ which is:

☐ the language of a translation furnished for the purposes of international search (under Rule 23.1(b)).

☐ the language of publication of the international application (under Rule 48.3(b)).

☐ the language of the translation furnished for the purposes of international preliminary examination (under Rules 55.2 and/or 55.3).

3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

☐ contained in the international application in written form.

☐ filed together with the international application in computer readable form.

☐ furnished subsequently to this Authority in written form.

☐ furnished subsequently to this Authority in computer readable form.

☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.

☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. ☐ The amendments have resulted in the cancellation of:

☐ the description, pages _____

☐ the claims, Nos. _____

☐ the drawings, sheet/fig _____

5. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2 (c)).**

* *Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are annexed to this report since they do not contain amendments (Rules 70.16 and 70.17).*

** *Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.*

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.
PCT/SE02/00689

V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Claims	1-7	YES
	Claims		NO
Inventive step (IS)	Claims	1-7	YES
	Claims		NO
Industrial applicability (IA)	Claims	1-7	YES
	Claims		NO

2. Citations and explanations (Rule 70.7)

The following main documents were cited in the International Search Report:

D1 US 5135539 (CARPENTIER)
D2 FR 2710847 DEMANDEUR(S))

The documents cited represent background art.

The invention claimed in claims 1-7 is not disclosed by any of these documents.

None of the cited documents gives any indication towards the claimed artificial heart. No relevant combination of the cited documents would lead a person skilled in the art to the invention defined in the claims.

Therefore, the invention claimed in claims 1-7 is novel and is considered to involve an inventive step. The invention is also considered to be industrially applicable.

CLAIMS

1. Heart prosthesis/artificial heart comprising a series of drawing and pressing means and intended to be implanted in a patient to replace the pumping acitivity of a heart, whereby comprises at least two compartments (5, 6, 12, 13, 25, 26, 27, 28), substantially surrounded by rigid-wall provided house (2, 3, 31) containing a number of drawing and/or pressing devices (10, 48, 50),
characterized in
that it comprises two halves, comprising an atrium (25, 26), and ventricles (27, 28) respectively, separated with a valve (29, 40) provided plate (37) which plate (37) is arranged to be able to be moved between the ventricles (27, 28) and the atriums (25, 26) by means of drawing and/or pressing devices (48, 50) arranged in said rigid wall provided house (31).

2. Heart prosthesis according to claim1,
characterized in
that it comprises four compartments (5, 6, 12, 13, and 25, 26, 27, 28, respectively).

3. Heart prosthesis according to claim1,
characterized in
that the drawing and/or pressing devices (10, 48, 50) are drawing and pressing electromechanical devices, respectively, including electro-magnets.

4. Heart prosthesis according to claim1,
characterized in
that said plate (37) is arranged to be moved by means of electro-magnets (48) or a hydraulic device arranged in said wall (31).

5. Heart prosthesis according to claim1,
characterized in
that the drawing and/or pressing devices are drawing, and pressing, respectively, hydraulically activated pistons.

6. Heart prosthesis according to claim1,
characterized in
that it is arranged to be controlled digitally via a soft-ware present in a circuit board (22) in a diastole, atrium systole, and systole phase, respectively.

7. Heart prosthesis according to claim1,
characterized in
that it is supplied with energy from one or more DC batteries.

PCT

COPY REQUEST

The undersigned requests that the present international application be processed according to the Patent Cooperation Treaty.

For receiving Office use only

International Application No.

International Filing Date

Name of receiving Office and "PCT International Application"

Applicant's or agent's file reference *(if desired) (12 characters maximum)* P16203PC00/CA

Box No. I TITLE OF INVENTION

ARTIFICAL HEART

Box No. II APPLICANT [X] This person is also inventor

Name and address: *(Family name followed by given name; for a legal entity, full official designation. The address must include postal code and name of country. The country of the address indicated in this Box is the applicant's State (that is, country) of residence if no State of residence is indicated below.)*

AL-NAJJAR, Azad
Rönnbergsgatan 54
S-723 46 VÄSTERÅS
Sweden

Telephone No.

Facsimile No.

Teleprinter No.

Applicant's registration No. with the Office

State *(that is, country)* of nationality: SE

State *(that is, country)* of residence: SE

This person is applicant for the purposes of: [X] all designated States [ ] all designated States except the United States of America [ ] the United States of America only [ ] the States indicated in the Supplemental Box

Box No. III FURTHER APPLICANT(S) AND/OR (FURTHER) INVENTOR(S)

Name and address: *(Family name followed by given name; for a legal entity, full official designation. The address must include postal code and name of country. The country of the address indicated in this Box is the applicant's State (that is, country) of residence if no State of residence is indicated below.)*

This person is:
[ ] applicant only
[ ] applicant and inventor
[ ] inventor only *(If this check-box is marked, do not fill in below.)*

Applicant's registration No. with the Office

State *(that is, country)* of nationality:

State *(that is, country)* of residence:

This person is applicant for the purposes of: [ ] all designated States [ ] all designated States except the United States of America [ ] the United States of America only [ ] the States indicated in the Supplemental Box

[ ] Further applicants and/or (further) inventors are indicated on a continuation sheet.

Box No. IV AGENT OR COMMON REPRESENTATIVE; OR ADDRESS FOR CORRESPONDENCE

The person identified below is hereby/has been appointed to act on behalf of the applicant(s) before the competent International Authorities as: [X] agent [ ] common representative

Name and address: *(Family name followed by given name; for a legal entity, full official designation. The address must include postal code and name of country.)*

STRÖM & GULLIKSSON IP AB
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S-417 64 GÖTEBORG
Sweden

Telephone No. +46-31-507700

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Teleprinter No.

Agent's registration No. with the Office

[ ] **Address for correspondence:** Mark this check-box where no agent or common representative is/has been appointed and the space above is used instead to indicate a special address to which correspondence should be sent.

Box No. V DESIGNATION OF STATES *Mark the applicable check-boxes below; at least one must be marked.*

The following designations are hereby made under Rule 4.9(a):

Regional Patent

☒ AP ARIPO Patent: GH Ghana, GM Gambia, KE Kenya, LS Lesotho, MW Malawi, MZ Mozambique, SD Sudan, SL Sierra Leone, SZ Swaziland, TZ United Republic of Tanzania, UG Uganda, ZM Zambia, ZW Zimbabwe, and any other State which is a Contracting State of the Harare Protocol and of the PCT *(if other kind of protection or treatment desired, specify on dotted line)* .....

☒ EA Eurasian Patent: AM Armenia, AZ Azerbaijan, BY Belarus, KG Kyrgyzstan, KZ Kazakhstan, MD Republic of Moldova, RU Russian Federation, TJ Tajikistan, TM Turkmenistan, and any other State which is a Contracting State of the Eurasian Patent Convention and of the PCT

☒ EP European Patent: AT Austria, BE Belgium, CH & LI Switzerland and Liechtenstein, CY Cyprus, DE Germany, DK Denmark, ES Spain, FI Finland, FR France, GB United Kingdom, GR Greece, IE Ireland, IT Italy, LU Luxembourg, MC Monaco, NL Netherlands, PT Portugal, SE Sweden, TR Turkey, and any other State which is a Contracting State of the European Patent Convention and of the PCT

☒ OA OAPI Patent: BF Burkina Faso, BJ Benin, CF Central African Republic, CG Congo, CI Côte d'Ivoire, CM Cameroon, GA Gabon, GN Guinea, GQ Equatorial Guinea, GW Guinea-Bissau, ML Mali, MR Mauritania, NE Niger, SN Senegal, TD Chad, TG Togo, and any other State which is a member State of OAPI and a Contracting State of the PCT *(if other kind of protection or treatment desired, specify on dotted line)* .....

National Patent *(if other kind of protection or treatment desired, specify on dotted line)*:

☒ AE United Arab Emirates
☒ AG Antigua and Barbuda
☒ AL Albania .....
☒ AM Armenia .....
☒ AT Austria and utility model
☒ AU Australia .....
☒ AZ Azerbaijan .....
☒ BA Bosnia and Herzegovina .....
☒ BB Barbados
☒ BG Bulgaria .....
☒ BR Brazil .....
☒ BY Belarus .....
☒ BZ Belize .....
☒ CA Canada
☒ CH & LI Switzerland and Liechtenstein
☒ CN China .....
☒ CO Colombia
☒ CR Costa Rica .....
☒ CU Cuba .....
☒ CZ Czech Republic and utility mod
☒ DE Germany and utility model
☒ DK Denmark and utility model
☒ DM Dominica
☒ DZ Algeria .....
☒ EC Ecuador .....
☒ EE Estonia and utility model
☒ ES Spain .....
☒ FI Finland and utility model
☒ GB United Kingdom
☒ GD Grenada
☒ GE Georgia .....
☒ GH Ghana .....
☒ GM Gambia
☒ HR Croatia .....
☒ HU Hungary .....
☒ ID Indonesia
☒ IL Israel .....
☒ IN India .....
☒ IS Iceland
☒ JP Japan .....
☒ KE Kenya .....
☒ KG Kyrgyzstan .....
☒ KP Democratic People's Republic of Korea .....
☒ KR Republic of Korea .....
☒ KZ Kazakhstan .....
☒ LC Saint Lucia
☒ LK Sri Lanka
☒ LR Liberia
☒ LS Lesotho .....
☒ LT Lithuania
☒ LU Luxembourg
☒ LV Latvia
☒ MA Morocco .....
☒ MD Republic of Moldova .....
☒ MG Madagascar .....
☒ MK The former Yugoslav Republic of Macedonia .....
☒ MN Mongolia
☒ MW Malawi .....
☒ MX Mexico .....
☒ MZ Mozambique
☒ NO Norway
☒ NZ New Zealand .....
☒ OM Oman
☒ PH Philippines .....
☒ PL Poland .....
☒ PT Portugal .....
☒ RO Romania
☒ RU Russian Federation .....
☒ SD Sudan
☒ SE Sweden
☒ SG Singapore
☒ SI Slovenia .....
☒ SK Slovakia and utility model
☒ SL Sierra Leone .....
☒ TJ Tajikistan .....
☒ TM Turkmenistan .....
☒ TN Tunisia
☒ TR Turkey .....
☒ TT Trinidad and Tobago .....
☒ TZ United Republic of Tanzania
☒ UA Ukraine .....
☒ UG Uganda .....
☒ US United States of America .....
☒ UZ Uzbekistan .....
☒ VN Viet Nam .....
☒ YU Yugoslavia .....
☒ ZA South Africa .....
☒ ZM Zambia
☒ ZW Zimbabwe .....

Check-boxes below reserved for designating States which have become party to the PCT after issuance of this sheet:

☐ ..... ☐ ..... ☐ .....
☐ ..... ☐ ..... ☐ .....

Precautionary Designation Statement: In addition to the designations made above, the applicant also makes under Rule 4.9(b) all other designations which would be permitted under the PCT except any designation(s) indicated in the Supplemental Box as being excluded from the scope of this statement. The applicant declares that those additional designations are subject to confirmation and that any designation which is not confirmed before the expiration of 15 months from the priority date is to be regarded as withdrawn by the applicant at the expiration of that time limit. *(Confirmation (including fees) must reach the receiving Office within the 15-month time limit.)*

See Notes to the request form

Box No. VI PRIORITY CLAIM

The priority of the following earlier application(s) is hereby claimed:

Filing date of earlier application (day/month/year)	Number of earlier application	Where earlier application is:		
		national application: country	regional application: * regional Office	international application: receiving Office
item (1) 10.04.2001	0101259-0	Sweden		
item (2)				
item (3)				
item (4)				
item (5)				

☐ Further priority claims are indicated in the Supplemental Box.

The receiving Office is requested to prepare and transmit to the International Bureau a certified copy of the earlier application(s) *(only if the earlier application was filed with the Office which for the purposes of this international application is the receiving Office)* identified above as:

☐ all items ☒ item (1) ☐ item (2) ☐ item (3) ☐ item (4) ☐ item (5) ☐ other, see Supplemental Box

* *Where the earlier application is an ARIPO application, indicate at least one country party to the Paris Convention for the Protection of Industrial Property or one Member of the World Trade Organization for which that earlier application was filed (Rule 4.10(b)(ii)):* ....

Box No. VII INTERNATIONAL SEARCHING AUTHORITY

Choice of International Searching Authority (ISA) *(if two or more International Searching Authorities are competent to carry out the international search, indicate the Authority chosen; the two-letter code may be used):*

ISA / SE

Request to use results of earlier search; reference to that search *(if an earlier search has been carried out by or requested from the International Searching Authority):*

Date *(day/month/year)* Number Country *(or regional Office)*

Box No. VIII DECLARATIONS

The following **declarations** are contained in Boxes Nos. VIII (i) to (v) *(mark the applicable check-boxes below and indicate in the right column the number of each type of declaration)*:		Number of declarations
☐ Box No. VIII (i)	Declaration as to the identity of the inventor	:
☐ Box No. VIII (ii)	Declaration as to the applicant's entitlement, as at the international filing date, to apply for and be granted a patent	:
☐ Box No. VIII (iii)	Declaration as to the applicant's entitlement, as at the international filing date, to claim the priority of the earlier application	:
☐ Box No. VIII (iv)	Declaration of inventorship (only for the purposes of the designation of the United States of America)	:
☐ Box No. VIII (v)	Declaration as to non-prejudicial disclosures or exceptions to lack of novelty	:

Box No. IX CHECK LIST; LANGUAGE OF FILING

This international application contains:

(a) the following number of sheets in paper form:

request (including declaration sheets)	:	4
description (excluding sequence listing part)	:	13
claims	:	2
abstract	:	1
drawings	:	12
Sub-total number of sheets	:	32
sequence listing part of description *(actual number of sheets if filed in paper form, whether or not also filed in computer readable form; see (b) below)*	:	
Total number of sheets	:	32

(b) sequence listing part of description filed in computer readable form

(i) ☐ only (under Section 801(a)(i))

(ii) ☐ in addition to being filed in paper form (under Section 801(a)(ii))

Type and number of carriers (diskette, CD-ROM, CD-R or other) on which the sequence listing part is contained *(additional copies to be indicated under item 9(ii), in right column)*: .....

This international application is accompanied by the following item(s) *(mark the applicable check-boxes below and indicate in right column the number of each item)*:

		Number of items
1. ☒ fee calculation sheet	:	1
2. ☐ original separate power of attorney	:	
3. ☐ original general power of attorney	:	
4. ☐ copy of general power of attorney; reference number, if any:	:	
5. ☐ statement explaining lack of signature	:	
6. ☐ priority document(s) identified in Box No. VI as item(s):	:	
7. ☐ translation of international application into *(language)*:	:	
8. ☐ separate indications concerning deposited microorganism or other biological material	:	
9. ☐ sequence listing in computer readable form (indicate also type and number of carriers (diskette, CD-ROM, CD-R or other))		
(i) ☐ copy submitted for the purposes of international search under Rule 13*ter* only (and not as part of the international application)	:	
(ii) ☐ *(only where check-box (b)(i) or (b)(ii) is marked in left column)* additional copies including, where applicable, the copy for the purposes of international search under Rule 13*ter*	:	
(iii) ☐ together with relevant statement as to the identity of the copy or copies with the sequence listing part mentioned in left column	:	
10. ☐ other *(specify)*:	:	

Figure of the drawings which should accompany the abstract: Fig. 1

Language of filing of the international application: Swedish

Box No. X SIGNATURE OF APPLICANT, AGENT OR COMMON REPRESENTATIVE

Next to each signature, indicate the name of the person signing and the capacity in which the person signs (if such capacity is not obvious from reading the request).

Gothenburg, April 4, 2002

Ulf Inger
Ström & Gulliksson IP AB

For receiving Office use only

1. Date of actual receipt of the purported international application:	2. Drawings: ☐ received:
3. Corrected date of actual receipt due to later but timely received papers or drawings completing the purported international application:	
4. Date of timely receipt of the required corrections under PCT Article 11(2):	☐ not received:
5. International Searching Authority (if two or more are competent): ISA /	6. ☐ Transmittal of search copy delayed until search fee is paid

For International Bureau use only

Date of receipt of the record copy by the International Bureau:

PATENT COOPERATION TREATY

COPY PCT

From the INTERNATIONAL BUREAU

To:

STRÖM & GULLIKSSON IP AB
Sjörporten 4
S-417 64 Göteborg
Sweden

INFORMATION CONCERNING ELECTED OFFICES NOTIFIED OF THEIR ELECTION

(PCT Rule 61.3)

Date of mailing (day/month/year)	
13 December 2002 (13.12.02)	
Applicant's or agent's file reference	**IMPORTANT INFORMATION**
P16203PC00/CA	
International application No.	**International filing date (day/month/year)** / **Priority date (day/month/year)**
PCT/SE02/00689	08 April 2002 (08.04.02) / 10 April 2001 (10.04.01)
Applicant	
AL-NAJJAR, Azad	

1. The applicant is hereby informed that the International Bureau has, according to Article 31(7), notified each of the following Offices of its election:

   EP :AT,BE,CH,CY,DE,DK,ES,FI,FR,GB,GR,IE,IT,LU,MC,NL,PT,SE,TR
   National :AU,BG,CA,CN,DE,GB,IL,JP,KP,KR,MN,NO,PL,RO,RU,SK,US

2. The following Offices have waived the requirement for the notification of their election; the notification will be sent to them by the International Bureau only upon their request:

   AP :GH,GM,KE,LS,MW,MZ,SD,SL,SZ,TZ,UG,ZM,ZW
   EA :AM,AZ,BY,KG,KZ,MD,RU,TJ,TM
   OA :BF,BJ,CF,CG,CI,CM,GA,GN,GQ,GW,ML,MR,NE,SN,TD,TG
   National :AE,AG,AL,AM,AT,AZ,BA,BB,BR,BY,BZ,CH,CO,CR,CU,CZ,DK,DM,DZ,EC,EE,
   ES,FI,GD,GE,GH,GM,HR,HU,ID,IN,IS,KE,KG,KZ,LC,LK,LR,LS,LT,LU,LV,MA,MD,MG,
   MK,MW,MX,MZ,NZ,OM,PH,PT,SD,SE,SG,SI,SL,TJ,TM,TN,TR,TT,TZ,UA,UG,UZ,VN,YU,
   ZA,ZM,ZW

3. The applicant is reminded that he must enter the "national phase" **before the expiration of 30 months from the priority date** before each of the Offices listed above. This must be done by paying the national fee(s) and furnishing , if prescribed, a translation of the international application (Article 39(1)(a)), as well as, where applicable, by furnishing a translation of any annexes of the international preliminary examination report (Article 36(3)(b) and Rule 74.1).

   Some offices have fixed time limits expiring later than the above-mentioned time limit. For detailed information about the applicable time limits and the acts to be performed upon entry into the national phase before a particular Office, see Volume II of the PCT Applicant's Guide.

   The entry into the European regional phase is postponed **until 31 months from the priority date** for all States designated for the purposes of obtaining a European patent.

The International Bureau of WIPO
34, chemin des Colombettes
1211 Geneva 20, Switzerland
Facsimile No.: (41-22) 740.14.35

Authorized officer:
ALI SOLEIMAN
Telephone No. (41-22) 338.83.38

WO 02/085432
PCT/SE02/00689

COPY

PATENT COOPERATION TREATY

PCT

From the INTERNATIONAL BUREAU

To:
STRÖM & GULLIKSSON IP AB
Sjörporten 4
S-417 64 Göteborg
Sweden

ANKOM
2002 -11- 08
Ström & Gullikson IP AB

NOTICE INFORMING THE APPLICANT OF THE COMMUNICATION OF THE INTERNATIONAL APPLICATION TO THE DESIGNATED OFFICES

(PCT Rule 47.1(c), first sentence)

Date of mailing (day/month/year)	IMPORTANT NOTICE
31 October 2002 (31.10.02)	
Applicant's or agent's file reference: P16203PC00/CA	

International application No.	International filing date (day/month/year)	Priority date (day/month/year)
PCT/SE02/00689	08 April 2002 (08.04.02)	10 April 2001 (10.04.01)

Applicant: AL-NAJJAR, Azad

1. Notice is hereby given that the International Bureau has **communicated**, as provided in Article 20, the international application to the following designated Offices on the date indicated above as the date of mailing of this notice:
   KP,KR,US

   In accordance with Rule 47.1(c), third sentence, those Offices will accept the present notice as conclusive evidence that the communication of the international application has duly taken place on the date of mailing indicated above and no copy of the international application is required to be furnished by the applicant to the designated Office(s).

2. The following designated Offices have waived the requirement for such a communication at this time:
   AE,AG,AL,AM,AP,AT,AU,AZ,BA,BB,BG,BR,BY,BZ,CA,CH,CN,CO,CR,CU,CZ,DE,DK,DM,DZ,EA,EC, EE,EP,ES,FI,GB,GD,GE,GH,GM,HR,HU,ID,IL,IN,IS,JP,KE,KG,KZ,LC,LK,LR,LS,LT,LU,LV,MA, MD,MG,MK,MN,MW,MX,MZ,NO,NZ,OA,OM,PH,PL,PT,RO,RU,SD,SE,SG,SI,SK,SL,TJ,TM,TN,TR,TT, TZ,UA,UG,UZ,VN,YU,ZA,ZM,ZW

   The communication will be made to those Offices only upon their request. Furthermore, those Offices do not require the applicant to furnish a copy of the international application (Rule 49.1(a-bis)).

3. Enclosed with this notice is a copy of the international application as published by the International Bureau on
   31 October 2002 (31.10.02) under No. WO 02/085432

4. **TIME LIMITS for filing a demand for international preliminary examination and for entry into national phase**

   The applicable time limit for entering the national phase will, subject to what is said in the following paragraph be **30 MONTHS** from the priority date, not only in respect of any elected Office if a demand for international preliminary examination is filed before the expiration of **19 months** from the priority date, but also in respect of any designated Office, in the absence of filing of such demand, where Article22(1) as modified with effect from 1 April 2002 applies in respect of the designated Office. For further details, see PCT Gazette No.44/2001 of 1 November 2001, pages 19926, 19932 and 19934, as well as the PCT Newsletter, October and November 2001 and February 2002 issues.

   In practice, **time limits other than the 30-month time limit** will continue to apply, for various periods of time, in respect of certain designated or elected Offices. For **regular updates on the applicable time limits** (20,21,30 or 31 months , or other time limit), Office by Office, refer to the PCT Gazette, the PCT Newsletter and the PCT Applicant's Guide, Volume II, National Chapters, all available from WIPO's Internet site, at http://www.wipo.int/pct/en/index.html.

   For filing a **demand for international preliminary examination**, see the PCT Applicant's Guide, Volume I/A, Chapter IX. Only an applicant who is a national or resident of a PCT Contracting State which is bound by Chapter II has the right to file a demand for international preliminary examination (at present, all PCT Contracting States are bound by Chapter II.)

   It is the applicant's **sole responsibility** to monitor all these limits.

The International Bureau of WIPO
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1211 Geneva 20, Switzerland
Facsimile No. (41-22) 740.14.35

Authorized officer
J. Zahra
Telephone No. (41-22) 338.81.11

(12) INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(19) World Intellectual Property Organization
International Bureau

(43) International Publication Date
31 October 2002 (31.10.2002)

PCT

(10) International Publication Number
WO 02/085432 A1

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0101259-0 10 April 2001 (10.04.2001) SE

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(74) Agent: STRÖM & GULLIKSSON IP AB; Sjörporten 4, S-417 64 Göteborg (SE).

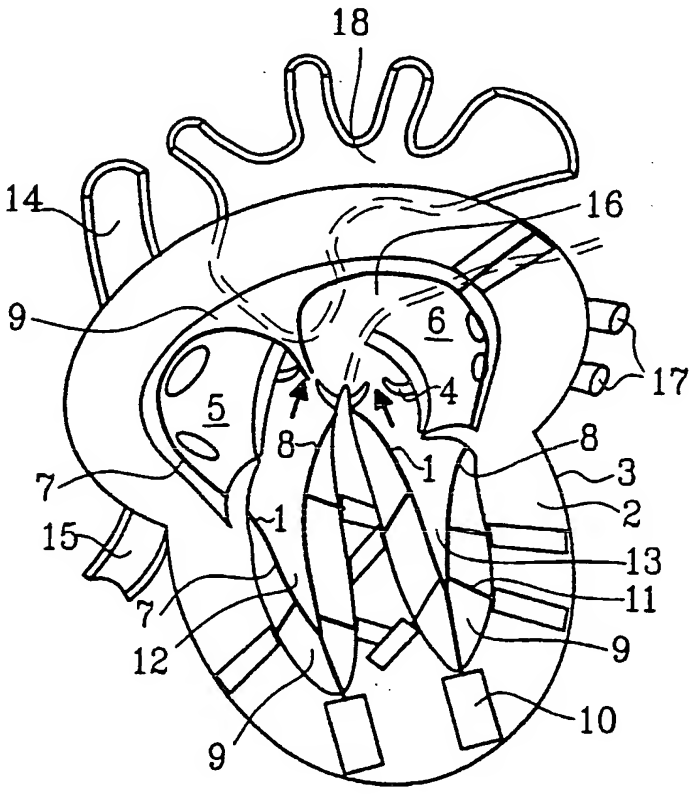
(81) Designated States *(national)*: AE, AG, AL, AM, AT (utility model), AT, AU, AZ, BA, BB, BG, BR, BY, BZ, CA, CH, CN, CO, CR, CU, CZ (utility model), CZ, DE (utility model), DE, DK (utility model), DK, DM, DZ, EC, EE (utility model), EE, ES, FI (utility model), FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, MZ, NO, NZ, OM, PH, PL, PT, RO, RU, SD, SE, SG, SI, SK (utility model), SK, SL, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VN, YU, ZA, ZM, ZW.

(84) Designated States *(regional)*: ARIPO patent (GH, GM, KE, LS, MW, MZ, SD, SL, SZ, TZ, UG, ZM, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE, TR), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG).

Published:
— *with international search report*

[Continued on next page]

(54) Title: ARTIFICIAL HEART



(57) Abstract: The present invention relates to a heart prosthesis/artificial heart comprising a series of drawing and pressing means and intended to be implanted in a patient to replace the pumping activity of a heart, whereby it comprises at least two compartments (5, 6, 12, 13, 25, 26, 27, 28), substantially surrounded by rigid-wall provided house (2, 3, 31) containing a number of drawing and/or pressing deivces (10, 48, 50), which are partly fixedly attached to said rigid-wall provided house (2, 3, 31), partly fixedly attached to a flexible, elastic wall layer (7, 30) arranged in the respective compartment, whereby the drawing and/or pressing devices (10, 48, 50) are arranged to draw said elastic wall layer (7, 30) towards said rigid-wall provided house (2, 3, 31) for filling said compartments (12, 13, 27, 28).

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For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

TITLE
ARTIFICIAL HEART

DESCRIPTION

Technical field

The present invention relates to an artificial heart comprising a series of towing and pressing means and intended to be implanted in a patient to replace the pumping acitivity of a heart.

The object of the present invention is to obtain an artificial heart to be implanted into a patient to replace whole of or part of the activity of a heart.

Background of the invention

The last years there has been an increased demand within cardiology for an efficient heart prosthesis.

Heart diseases and often in combination with circulatory diseases give raise to a serious threat against the patient's life.

Heart failure, as a result of a longterm weakness of the function of the heart, is a very serious condition and will sooner or later lead to death.

Access to healthy donator hearts is also very restricted and a patient may have to wait for several years for a suitable heart to be presented for implantation.

For these reasons it is of great importance to find and develop an artificial heart or rather an apparatus which can offer a continuous, harmless, comfortable, and reliable substitute for a weak, failing heart.

For many years a number of artificial heart prosthesis have been introduced. However, these show a number of deficiencies and drawbacks, such as lack of impantability, lack of physiological pliability, lack of longterm use as well as lack of pliability with regard to beat-volume.

US-A-5,139,517 shows an artificial heart which is hydraulically operated by activation from a pacemaker.

US-A-5,135,539 shows a heart prosthesis working with an electromechanical device in the form of a hydraulic micropump.

FR-A-2,710,847 shows an artificial heart having two different sacks and being operated by hydraulic oil.

US-A-4,809,676 shows a device to be implanted around aorta and which is controlled by a series of electro-magnets placed opposite each other. When the electro-magnets are activated aorta will be compressed between these so that a pumping movement is obtained.

WO 99/55399 shows an electro-magnetically controlled heart assistance technology where a number of electro-magnets are placed on the outside of the living heart, which means that one has an electro-magnetically supported heart.

US-A-6,099,460 shows an artificial heart having flexible outer walls which are influenced by electro-magnets, partly applied on the outer walls of the flexible walls, partly applied on the inside of the heart.

US-A-6,123,724 shows a construction to influence a heart by means of electro-magnetic coils attached to the ribs and permanent magnets placed adjacent the electro-magnetic coils. It is hereby a matter of supporting function when the normal pacing of a heart does not function.

US-A-6,197,055 relates to a single chamber prosthesis having a movable wall which obtains pumping by being turned from one side to the other.

US-A-5,383,840 relates to a heart supporting construction having a compression pad to surround a common heart by means of which compression pad the pumping of the heart is obtained.

None of these references discloses a rigid-wall provided prosthesis having a inner flexible compartments.

Description of the present invention

It has now surprisingly been shown possible to be able to solvet hese abovementioned deficiences by means of the present invention, which is characterized in that it comprises at least two compartments, substantially surrounded by rigid-wall provided house containing a number of electro-magnets, which are partly fixedly attached to said rigid-wall provided house, partly fixedly attached to a flexible, elastic wall layer arranged in the respective compartment, whereby the electro-magnets are arranged to draw said elqastic wall layer towards said rigid-wall provided house for filling said compartments.

The present invention will now be described more in detail in the following with reference to the accompanying drawing, wherein

FIG. 1 shows a first embodiment of the present invention in a ventricular systole phase;

FIG. 2 shows the embodiment of FIG. 1 in an atrial systole phase;
FIG. 3 shows an electro-magnet, drawing, used in the present invention in a drawing, activated position;
FIG. 4 shows an electro-magnet, drawing, in accordance with FIG. 3 in a non-drawing, inactivated position;
FIG. 5 shows an implanted heart prosthesis according to the invention with a control unit;
FIG. 6 shows a second embodiment of the invention comprising a further whole prosthesis in a diastole phase;
FIG. 7 shows the embodiment of FIG. 6 in a systole phase;
FIG. 8 shows the embodiment of FIG. 6 and 7 in a cross-section;
FIG. 9 shows a second electro-magnet, pressing, used in the second embodiment of the present invention according to FIG. 6 in an inactivated position;
FIG. 10 shows the electro-magnet according to claim 9 in a pressing, activated position;
FIG. 11 shows the embodiment of FIG. 6-8 in diastole phase (A), atrial systole phase (B) and ventricular systole phase (C);
FIG. 12 shows the embodiment according to FIG. 1-2 in diastole phase (A), atrial systole phase (B) and ventricular systole phase (C);
FIG. 13 shows generally an AV-plane of a heart and its function in one position;
FIG. 14 shows the embodiment of FIG. 13 in a second position;
FIG. 15 shows a partial prosthesis where the atrium of the former heart remains;
FIG. 16 shows a further embodiment using a divisible prosthesis; and
FIG. 17 shows a further embodiment of a partial prosthesis.

The actual function of the present invention is clearly apparent from the figures shown, as well as from the following disclosure of the natural circulation system.

The heart is surrounded by the heart sac, the pericardium, whereby the heart contains four cavities, right atrium, right ventricle, left atrium and left ventricle. The atriums are divided by the thin walled atrial septum, while the ventricles are separated by a thick walled ventricular septum. In the right atrium the two vena cavas, vena cava superior och vena cava inferior, end. From the right atrium the blood flows through the tricuspidalisostium with its valve equipment (valvula tricuspidalis) to the right ventricle from where it is then pumped via the pulmonalisostium and its valves (valvula pulmonalis) to the pulmonary artery (arteria pulmonalis).

The oxygenated blood from the lungs flows via the four pulmonary veins (venae pulmonalis) to the left atrium and then further to the left ventricle through the mitralis valve (valvula mitralis). The left ventricle is ellipsoidal in shape and not so trabecular as the right ventricle. Its myocardium, mucle wall, is 3-5 times thicker than the one of the right ventricle, which is due to the higher pressure work carried out in the left ventricle. It should be noted that the

left ventricle is dorsally placed, while the right ventricle is ventrally placed. From the left ventricle the blood is pumped out into the large body artery, the aorta.

The task of the heart is keep the blood circulating in the body. From a physiological point of view, it consists of two pumps connected in series, the right heart and the left heart. The atriums operate as reservoirs to the ventricles and facilitate a rapid filling of these during the filling phase of the heart, diastole. During the ejection phase, systole, the blood is driven with a high speed out into the aorta and arteria pulmonalis.

During rest the heart pumps 4-5 litres per minute. The blood pressure in the right ventricle during systolic phase is 15-30 mm Hg while it is 120-150 mm Hg during systolic phase in the left ventricle.

The heart cycle is normally divided into two phases, diatole – the filling of the ventricles – and systole – the emptying of the ventricles. Diastole, in turn, can be divided into three parts, viz. a first third part, a second third part and a last third part, whereby the atriums during the last third part are contracted (atrial systole).

Phase 1 diastole			Phase 2 systole
First third partl Rapid filling	Second third part	Last third part Atrial contraction	Contraction of the ventricles

In the present description the heart cycle is divided into three phases to be able to compare the natural cycle with cycle/function of the artificial heart. Hereby the three phases are diastole, atrial systole and ventricular systole

Phase 1 diastole	Phase 2 atrial systole	Phase 3 ventricular systole

The three phases of the heart rhythm are:
Diastole: During the first phase of the heart rythm, diastole, the heaert is filled with blood, and during the greater part of diastole the blood flows in the atriums and through the valves between the atriums and the ventricles.

Atrial systole: The subsequent phase is called atrial systole when the atriums contract so that the remaining blood is pressed into the ventricles.

Ventricular systole: At the end of the atrial systole and after a short delay the ventriles start to contract, whereby the pressure therein is higher than in the atriums, and the valves between the atriums and the ventricles are closed and the blood is forced out of the heart in into the pulmonary artery, *arteria pulmonalis*, and into the large body artery, *aorta*.

The natural heart contraction is released by electrical signals (action potentials) which derive from the sinoatrial bundle, which is a small collection of cells, which depolarize themselves so that action potentials are released. The sinoatrial bundle is present in the right atrium adjacent the mouth of *vena cava superior*. When action potentials have been created in the sinoatrial bundle, these will spread through the whole heart in a system of specialized muscle cells which lead these impulses through the heart and release a contraction. The sinoatrial bundle is thereby the natural pace-maker of the heart (frequency determinator). Generally, the sinoatrial bundle provides 60-70 impulses per minute.

The most known idea concerning pumping of blood from the heart has been what is called Asqueezing motion®, i.e., one has regarded the pumping e.g., from the left ventricle as a contraction of the volume of the ventricle by a contraction of the walls of the ventricle. This hypothesis has now, however, been modified.

In 1932 Hamilton & Rompf proved the importance of the long axis contraction of the left ventricle. Their principle of the pumping of the heart has then formed the basis for a larger research work during the later years.

From animal experiments one has thus drawn the conclusions that:

- the heart maintains a constant volume during both the diastole and the systole phases;
- the main pumping function of the heart depends on a caudocephaladic movement of the atrioventricular plane (54 i fig. 13, 14). This movement in turn provides a reciprocal effect of two compartments so that the atriums are filled during the systole phase of the ventricles and that the ventricles are filled at a simultaneous reduction of the volumes of the atriums in diastole phase.
- The atrioventricular plane moves towards the tip of the heart, apex, during systole while the tip of the heart moves inconsiderably during systole and diastole (about 1 mm).

Hoffman and Ritman (1985) carried out a study on dogs and arrived to the fact that the tip of the heart, apex, is maintained rather stable while the atrioventruclar plane moves towards apex during systole and towards the atriums during diastole, when the atriums and the ventricles are are emptied and filled, alternatively.

Hamilton and Rompf draw their conclusion from animal experiments, but so did also Hoffman and Ritman. But the systolic shortening of the longitudinal axis of the ventricles, i.e., the down going movement of the base of the heart towards apex during systole has been studied on humans using different techniques.

The most extensive studies with regard hereto during the last years have been carried out by Lundbäck (1986). He proved the model of ventricular pumping, the same as previously presented by Hamilton and Rompf, and Hoffman and Ritman, respectively. These studies prove the importance of a longitudinal axis contraction and the systolic movement of the atrioventrcular plane towards apex, and that the heart, simultaneously herewith, maintains a constant volume during both diatole and systole, thanks to the heart sac, the pericardium, and the support from surrounding tissues., (Wandt, Birger, Mitral Ring Motion in Assessment of Left Ventricular Function, Linköping 1998).

During early diastole phase, fig. 14, the atrioventricular plane (the AV-plane) moves with its prosthesis valves in the heart rapidly upward towards the atriums. At the end of the diastole phase the AV-plane moves still more as a result of the contraction which occurs in the atriums. In his study of the left ventricle, Lundbäck has noticed that the left ventricle has an outer diameter of about 68 mm in a healthy young person. In this way the left ventricle contracts during systolic phase in a substantially cylindrical segment having a length of 19 to 22 mm (longitudinally) and having a radius of about 34 mm. The cylindrical segment has a volume of 69 to 80 ml which value corresponds with the normal value of the stroke volume of a healthy young person, i.e., the stroke volume is determined by the longitudinal movement of the AV-plane as well as of its surface in the left ventricle. (Wandt, Birger, Mitral Ring Motion in Assessment of Left Ventricular Function, Linköping 1998).

The present invention is a heart prosthesis which substantially eliminates or prevents the drawbacks and problem, which are connected with prior invented and evaluated heart prosthesis.

Fig. 1, 2, 6, 7, 8, 11, 12 show the present invention in its entirety, while fig. 3, 4, 5, 9, 10, show certain details of an embodiment of the invention, fig. 13, 14 show, generally an AV-plane in a heart and its function according to Hoffman and Ritman-s, Hamilton and Rompf-s, and Lundbäck-s hypothesis of heart physiology.

The present invention is a completely implantable heart prosthesis which replaces the natural heart, completely or partly. The outer wall 2 of the prosthesis is created of a rigid, or semi-rigid material, such as a biocompatible polymer and is with regard to size and form about proportional to the natural heart. The outer layer 3 of the walls being in contact with

body tissues is construed of a biocompatible thermoplastic material.

The prosthesis consists of two ventricles each being provided with two openings equipped with artifical valves 4. Through one of the openings blood is pumped out and through the other one blood is received. Further, there are two further compartments, comparable to the natural atriums, whereby the right atrium 5 of the prosthesis is provided with three openings. Off these, is one an opening for outgoing blood to the right ventricle 12 of the prosthesis, and two are inlet openings for blood into the atrium 5. Left atrium 6 comprises however, five openings, of which one is an outlet opening for blood to the left ventricle 13 and the other four are inlet openings through which blood passes from the two lungs to left atrium.

Each compartment of the four described above are provided with their separate activation and controlling device. This device is made of a flexible layer (wall) 7 of an elastic, biocompatible material which is utilized for pumping of blood. This layer 7 is fixed to the respective opening 8. The innermost layer 1 of this first mentioned layer 7 is in direct contact with the flowing blood and is construed of a hemocompatible material, whereby simulataneously a blood receiving compartment is formed. A free distance 9 is present between the inner side of the outer rigid wall 2 of the prosthesis and the said flexible layer 7.

To summarize, the artificial heart contains four compartments: one corresponding to right atrium 5, one which corresponds to right ventricle 12, one which corresponds to left atrium 6, and one which corresponds to left ventricle 13. In the right atrium of the prosthesis the two vena cava end, vena cava superior 14 and vena cava inferior 15. The rigid outer wall 7 of the prosthesis corresponds to the pericardium of the natural heart, while the flexible, elastic layer 7 surrounding the four compartments corresponds to the natural muscle walls, the myocardium, of the ventricles and the atriums.

From the right atrium 5 of the prosthesis blood flows through a prosthetic valve 4 to the right ventricle of the prosthesis from where it is then pumped to the pulmonary artery (arteria pulmonalis) 16 via the pulmonalisostium of the prosthesis, which is provided with a prosthetic valve.
The oxygenated blood from the lungs flows via the four pulmonary veins (venae pulmonalis) 17 to the left atrium 6 of the prosthesis and then further to the left ventricle 13 of the prosthesis through a prosthetic valve. The elastic layer of the left ventricle of the prosthesis should be 3 to 4 times as thick as the elastic layer of the right ventricle which is due to the higher pressure work at the left side compared to the right side. Left ventrile pumps blood into the large body artery, aorta 18.

The task of the artificial heart is to keep the blood circulating in the body and consists, for that reason, of two pumps connected in series, in the same way as the natural heart, a right and a left pump. The two atriums of the prosthesis serve as reservoirs for the ventricles of the prosthesis and facilitates a rapid filling of these during the filling phase of the prosthesis, diastole. During the ejection phase, systole, the blood is driven with a high speed out into aorta and arteria pulmonalis.

Within the hard wall 2 there is a number of mini electro-magnets 10 (cf in particular fig. 3 and 4). The material of the outer hard wall should then be a suitable thermoplastic material. The movable part of the magnets, the core 11, 19, is present in a fixed contact with the flexible, elastic layer 7. Each magnet 10 contains further a field conduit 20 surrounding the movable metallic core 11, 19.

The elctro-magnetic system is driven from an eletrical source 21. The current can be added in different ways, such as using compact, rechargeable batteries, or via a transformer with a rectifier, which adds a direct current. A smaller electrical conduit running intracutaneous from the inside of the body to its outside is surrounded by a biocompatible material, e.g., Dacron®. Alternatively, the power supply may carried out through transcutaneous transfer of electrical energy through the skin to specific electrodes underneath the skin, in which way the need for using an intra cutaneous running conduit will be eliminated.

The artificial heart functions according to the following.
The function of the artificial heart can be separated into three phases, in the same way as the function of the natural heart, as described above.

Diastole: During the diastole phase the elastic layer of the respective ventricle is contracted under influence of the electro-magnets (drawing magnets) in a direction towards the rigid outer walls (fig. 12A). Hereby the artificial heart is filled with blood. During the major part of diastole blood flows into the atriums and througfh the valves between atriums and ventricles.

Atrial systole: During this phase the effect of the electro-magnets (drawing magnets) on the elastic layer in the respective atrium (fig. 12B), whereby the elastic layer is resiliently returned so that remaining amount of blood in the respective atrium is pressed into the ventricles.

Ventricular systole: During this phase the effect of the electro-magnets on the elastic layer in the respective ventricle ceases (fig. 12C). Hereby, the elastic layer returns so that blood is forced out of the ventricles and into the pulmonary artery and aorta. Simultaneously, during this phase the elastic layer in the respective atrium is drawn (fig. 12C) by means of

the electro-magnets (drawing magnets) towards their outer rigid wall.

The pressure which is created in the respective ventricle is commonly about 100 to 120 mm Hg on the left side and 15 to 30 mm Hg on the right side. The pressure is separately controlled in the four respective compartments by means of the electro-magnets and by means of the thickness of the elastic walls (the thicker the wall, the higher the pressure). The number of electro-magnets connected to the respective compartment may also be varied depending on the thickness of the elastic layer and on the drawing-pressing-ability, as desired.

The core of the electro-magnets (the movable metallic core) is drawn out of the field conduit by means of the effect of the elastic layer (fig. 3). A conduit from the electro-magnets runs to a digital, electronic circuit board 22, the electronics of which is similar to previously known Acardiac pacing system® in pace-makers, and which regulates the frequency of the electrical impulses to the electro-magnetic system in the prosthesis/artificial heart.

Said digital electronic circuit board 22 produces and regulates pulses of electrical current to and through the electro-magnets, whereby a magnetic field is created which leads to that the metallic core is drawn into the field condit (fig. 4). This in turn leads to that the elastic layer is drawn towards the rigid outer wall.

The digital circuit board 22 receives an input signal from an electrode or sensor 23 which is placed in or adjacent the sinoatrial bundle to receive the natural electrical impulses (one may save that part of the right atrium comprising the sinoatrial bundle at a surgical extraction of the failing heart at the implantation of the prosthesis). Alternatively, one may use a blood pressure sensor 24 placed in the wall of the left arteria carotis communis. This sensor is sensitive to a variation of the blood pressure in arteria carotis communis. In this way the frequency of the impulses derived from the digital electronic circuit board to the electro-magnets, is controlled. Thereby, the prosthesis answers to an increase or decrease to the natural, physiological demand of the body.

The circuit board can be programmed so that the electro-magnets of the respective atrium and ventricle are separately activated. Furthermore, the size of the current activating the electro-magnets of the respective atrium and ventricle can be regulated each individually by providing a desired degree of drawing of the elastic layer towards the rigid outer wall.

An alternative embodiment of the present invention is by implanting only one two-compartment unit, e.g., only right and left ventricles. The two ventricles have, in such a case, the same criteria as described above. They are sutured to the natural respective atrium of the patient, whereby the valves between atriums and ventricles are present in the

prosthesis part. Hereby, the upper part of the heart prosthesis in such a way that there is only one ingoing opening on each side, one on the right side and one on theleft side. The ingoing openings are sewn up with the remaining natural atriums (left and right side). This technique helps in contributing to a faster, easier and more safe surgical technology (cf fig. 15)

In order to further improve the prosthesis the upper outer walls of the atriums can be construed in such a way that it consists of two, almost identical parts, which together forms the outer rigid wall of the atriums (cf fig. 16). Herein the parts has been denoted A and B. Part A is sewn up with the natural atrium and part B will be in a fixed relation to the remaining part of the pump/prosthesis. This technique facilitates optional future reoperations, if one should need to replace the whole or part of the prosthesis. One can replace damaged parts or the aprts one count on should need to be replaced after a certain time period, without need for removing part A, which is fixedly connected to the atrium. The only thing one needs to do is to screw loose part B from part A and remove the prosthesis including part B.

In accordance with another embodiment half of, or only a quarter of a heart be replaced using a prosthesis according to the present invention. Such a half prosthesis is shown in fig. 17. Two such half prosthesis may also form a total prosthesis.

A further embodiment of the invention is shown in fig. 6 and 7, which embodiment also is a completely implantable prosthesis, whereby it consists of two halves (right and left) where each half is divided into two compartments, corresponding to an atrium 25, 26 and one ventricle 27, 28. These compartments are connected with each other via a valve prosthesis 29, 40. The walls of the atriums and ventricles consist, as described above, of an elastic, flexible layer 30. Furthermore, there is an outer rigid wall 31, such as in the previously described embodiment, but contrary to that there is a slit 32 between the outer walls of the ventricles and the outer walls of the atriums. This slit is 10 to 20 mm. The walls of the atriums, the elastic wall, is fixed at the base of this prosthesis to the outer walls 33 of the atriums, simulataneously as the elastic walls of the ventricles are fixed to the outer walls of the ventricles in the apex of the prosthesis or its tip (lower end) 34.

Further there are a number of metal pins 35 having a diameter of one to some millimetres and having a length of 3 to 4 cm arranged to hold the outer walls of the atriums and the outer walls of the ventricles in fixed relation to each other. A thin layer 36 of the outer rigid wall covers the slit described on the outside of the prosthesis.

Further, there is a metallic plate 37 which corresponds to the atrioventricular plane 54 of the natural heart (fig. 13, 14), which plate has a thickness of one to some millimetres and

separates the atriums 25, 26 from the ventricles 27, 28. The elastic wall layer of the atriums is fixedly arranged to the upper side 38 of the metal plate 37 and the elastic wall layer of the ventricles is fixedly arranged to the lower side of the metal plate 37. The metal plate 37 can be exchanged to any other suitable material, which fulfils the demands of being long term lasting and feasibly non-elastic or flexible.

In the metal plate 37 there are two openings connecting the atriums 25, 26 of the prosthesis with the ventricles 27, 28 of the prosthesis with each other, one in each side. Theopenings correspond to the litralis valve29 and the tricuspidalis valve 40 and are each provided with vale prosthesis. Simultaneously, each ventricle has an outlet opening which is provided with valve prosthesis and which correspond to pulmonalis valve 41 on the right side, and the aorta valve 42 on the left side and which are arranged outside the metal plate 37 (fig. 8).

In the same way as in the above described embodiment this embodiment comprises four compartments: one 26 corresponding to the right atrium, one 28 corresponding to the right ventricle, one 25 corresponding to the left atrium and one 27 corresponding to the left ventricle. In the right atrium 26 of the prosthesis the two vena cavas end, vena cava superior 43 och vena cava inferior 44.

From the right atrium 26 blood flows through the valve prosthesis 40 to the right ventricle 28 of the prosthesis from whyere it is then, via the pulmonalisostium of the prosthesis being provided with a valve prosthesis 41 is pumped to the pulmonary artery (arteria pulmonalis) 45.

The oxygenated blood from the lungs flows via the four pulmonary veins (venae pulmonalis) 46 to the left atrium of the prosthesis and then further to the left ventricle 27 of the prosthesis through a valve prosthesis 29. The elastic layer of the left ventricle of the prosthesis should be 3-4 times thicker than that of the right ventricle, which is due to the larger pressure work carried out on the left side compared to the right side. Left ventricle pumps blood into the large body artery, aorta 47.

The task of the artificial heart is to keep blood circulating in the body and consists, for that reason, of two pumps connected in series, in the same way as the natural heart, one right and one left pump. The two atriums of the prosthesis serve as reservoirs for the ventricles of the prosthesis and facilitates a rapid filöling of these during the filling phase, diastole, of the prosthesis. During the ejection phase, systole, the blood is driven with a high speed out into aorta and arteria pulmonalis.

The outer rigid wall 31 of the prosthesis, in which the metal plate 31 of the prosthesis

moves to and fro, it corresponds to the surrounding sac, the pericardium, of the natural heart. In the same way the elastic wall 30 of the prosthesis corrsponds to the muscle wall, the myocardium, of the natural wall. As described above, the to and fro going movement of the metal plate within the slit 32 of the outer rigid wall of the prosthesis is similar to the movgement of the AV-plane of the natural heart according to the models of Hamilton and Rompf (1932), Hoffman and Ritman (1985) and Lundbäck (1986).

Unlike the first described embodiment, this embodiment shows some electro-magnets 48 (fig. 9 and 10) having an opposite function (pressing magnets) which are arranged to the upper edge (fig. 8) in the outer wall of the ventricles. The movable core 49 of the electro-magnets are fixed to the underside 39 of the metal plate. Further, there is a number of electro-magnets 50 (fig. 3 and 4) within each outer wall of the ventricles. The movable parts of these electro-magnets (drawing magnets) are present and fixed to the outside of the elastic wasll layer 30 of the ventricles.

In stead of pressing magnets placed outside of the ventricles in the rigid wall, drawing magnets can be placed outside the atriums in the upper edge of the rigid wall. Even combinations of drawing and pressing electro-magnets can be present.

Further, there is a number of electro-magnets 51 (drawing) in the outer wall of each atrium, the cores of which are fixedly arranged to the elastic wall layer 30 of the atriums.

The material of the outer wall 30 of the heart prosthesis should, as mentioned above, be made of a suitable, biocompatible thermo plastic material. Further, the elastic wall should as such or in a laminate has an Ahemokompatibel® surface directed to the respective compartment, which surface will be brought into cotact with blood.

Each electro-magnet of the type pressing magnet comprises a field conduit 52 surrounding the core 49. When the electro-magnets are arranged as pressing magnets the core is pressed into the field conduit by means metal plate by means the effect of the thick, elastic wall layer 30 of the ventriles (fig. 9), whereby they are prosthesissed out of the field conduit when current is allowed to pass through this (fig. 10). A conduit from the electro-magnets runs to a digital, electronic board 22, which corresponds to the board 22, fig. 5, of the embodiment first described.

The prosthesis can be driven in the same way as the first described embodiment.

This further embodiment functions as follows:
Diastole: In the beginning of diastole (fig. 11A) the metalplate is drawn up towards the lower edge of the outer wall of the atrium of the prosthesis by means of electro-magnets

(pressing) 48 and the elastic wall of the respective ventricle is drawn towards its hard rigid wall by means of the electoi-magnet 50 (drawing). During the first third part to the first half of the diastole phase of the prosthesis the filling of the ventricle is done very fast due to the blood collected in the atriums during the previous systole phase of the ventricles, and which is now pressed to the respective ventricle through valve prosthesis, which correspond to the mitralis 29 and tricuspidalis 40 valves, when trhe metal plate 37 is pushed upward towards the atriums by means of the magnetic force. Simultaneously, there is a reduction of the volumes of the atriums of the prosthesis, as the heart maintains a constant volume during both diatole and systole phases (acc. to Hoffman & Ritman, Hamilton et al, Lundbäck a.o.). Alternatively the metal plate 37 of the prosthesis can be pressed upward towards the atriums of the prosthesis in the beginning of the diatole phase by means of a hydraulic device being activated by means of an implanted mini hydraulic engine.

During the second third of the diatole a minor amount of blood is moved directly from the veins through the atriums to the ventricles.

Atrium systole: During the first phase (fig. 11B) the drawing effect of the electro-magnets 51 on the elastic wall layers of the respective atriums cease, whereby the elastic wall layers retains to a basic position, whereby the remaining part of the blood of the respective atrium is pressed into the respective ventricle.

Ventricle systole: During this phase (fig. 11C) the effect of the electro-magnets 50 in the outer rigid wall of the ventricles, ceases, whereby the elastic layer retains its basic position and the metal plate 37 is drawn to the ventriles (the apex of the prosthesis) by means of the effect by the thick elastic inner wall layers of the ventricles, and after ceased pressure influence of the pressing magnets 48. The inner wall layer hereby is resiliently returned and the blood is pressed out through the pulmonary artery 45 and aorta 47, when the valve prosthesis corresponding to the mitralis och tricupidalis valves have been closed. When the atrium systole phase of the atrium is finished the elastic wall layer of the atriums is drawn towards the outer hard rigid walls by means of the electro-magnets 51 present in the outer rigid walls of the atriums, whereby the pressure decreases in the respective atrium and the blood flows into the respective atrium of the prosthesis from the veins, vena cava superior, och vena cava inferior, and the pulmonary vein, venae pulmonalis.

The pressure being created in the respective ventricle is commonly 100 to 140 mm Hg on the left side and 15 to 30 mm Hg on the right side. The pressure is controlled separately in the four respective compartments depending on the thickness of the elastic walls, which can be the same or not in the different respectve compartments (the greater thickness, the larger pressure)

CLAIMS

1. Heart prosthesis/artificial heart comprising a series of drawing and pressing means and intended to be implanted in a patient to replace the pumping acitivity of a heart, **characterized** in
that it comprises at least two compartments (5, 6, 12, 13, 25, 26, 27, 28), substantially surrounded by rigid-wall provided house (2, 3, 31) containing a number of drawing and/or pressing devices (10, 48, 50), which are partly fixedly attached to said rigid-wall provided house (2, 3, 31), partly fixedly attached to a flexible, elastic wall layer (7, 30) arranged in the respective compartment, whereby the drawing and/or pressing devices (10, 48, 50) are arranged to draw said elqastic wall layer (7, 30) towards said rigid-wall provided house (2, 3, 31) for filling said compartments (12, 13, 27, 28).

2. Heart prosthesis according to claim1,
characterized in
that it comprises four compartments (5, 6, 12, 13, and 25, 26, 27, 28, respectively).

3. Heart prosthesis according to claim1,
characterized in
that the drawing and/or pressing devices (10, 48, 50) are drawing and pressing electromechanical devices, respectively, including electro-magnets.

4. Heart prosthesis according to claim1,
characterized in
that it comprises two halves, comprising an atrium (25, 26), and ventricles (27, 28) respectively, separated with a valve (29, 40) provided plate (37) which plate (37) is arranged to be able to be moved between the ventricles (27, 28) and the atriums (25, 26) by means of drawing and/or pressing devices (48, 50) arranged in said rigid wall provided house (31).

5. Heart prosthesis according to claim1,
characterized in
that said plate (37) is arranged to be moved by means of electro-magnets (48) opr a hydraulic device arranged in said wall (31).

6. Heart prosthesis according to claim1,
characterized in
that the drawing and/or pressing devices are drawing, and pressing, respectively, hydraulically activated pistons.

7. Heart prosthesis according to claim1,
characterized in
that it is arranged to be controlled digitally via a soft-ware present in a circuit board (22) in a diastole, atrium systole, and systole phase, respectively.

5

8. Heart prosthesis according to claim1,
characterized in
that it is supplied with energy from one or more DC batteries.

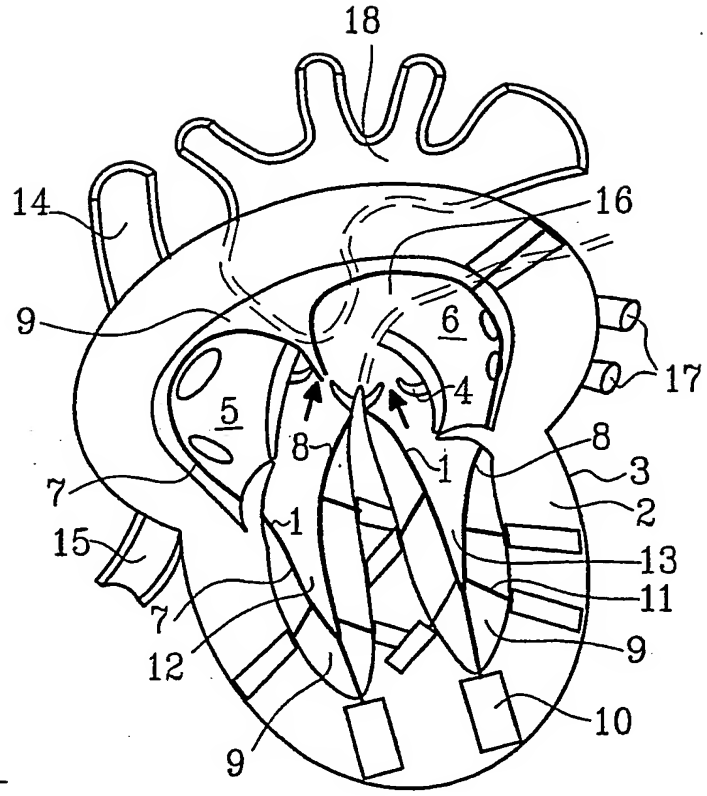
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FIG.1

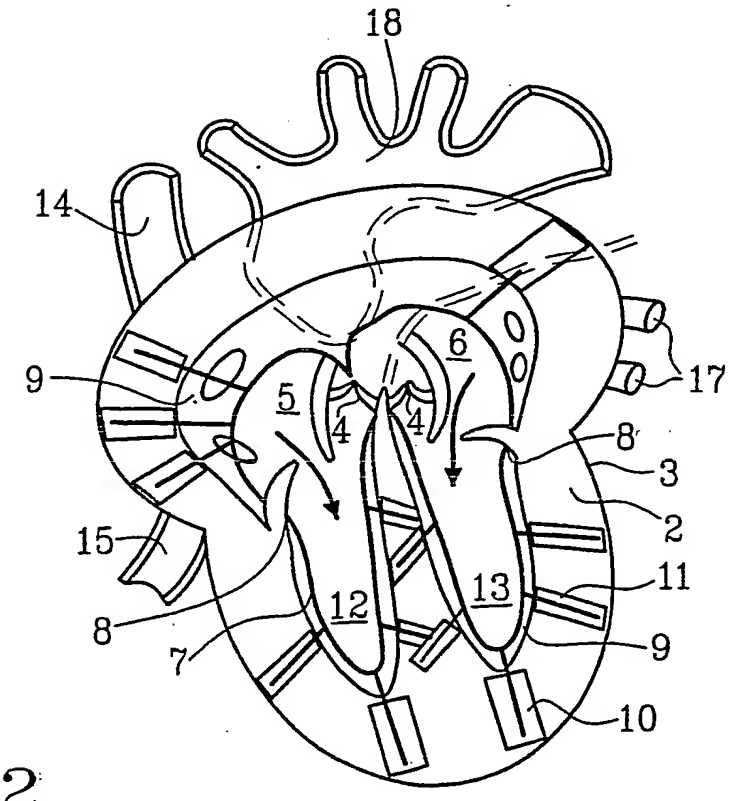
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FIG.2

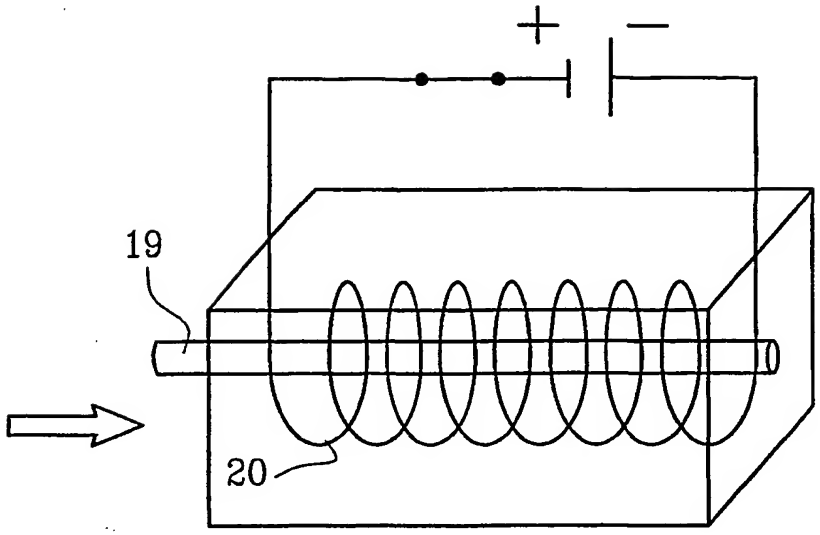


FIG.3

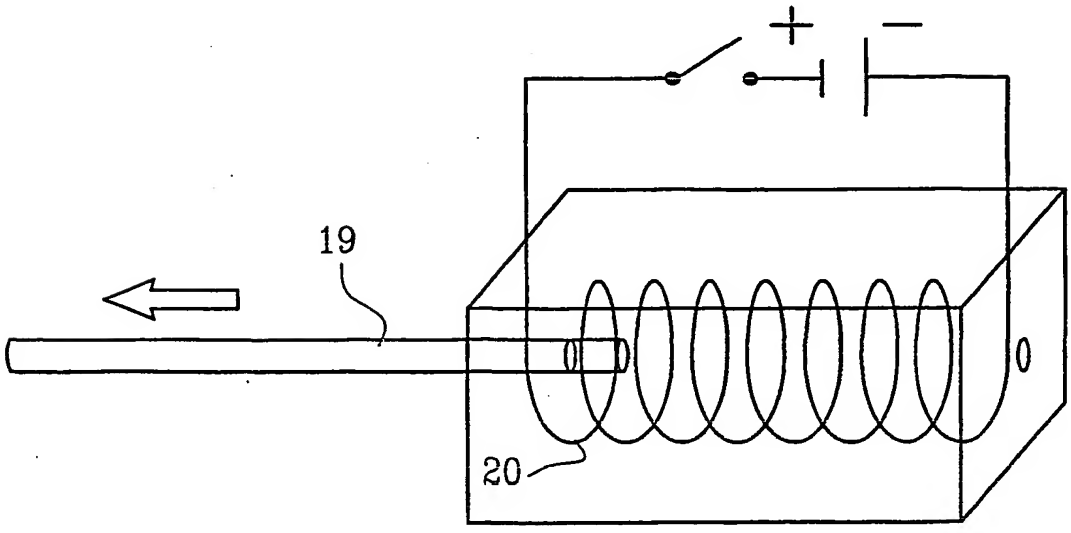
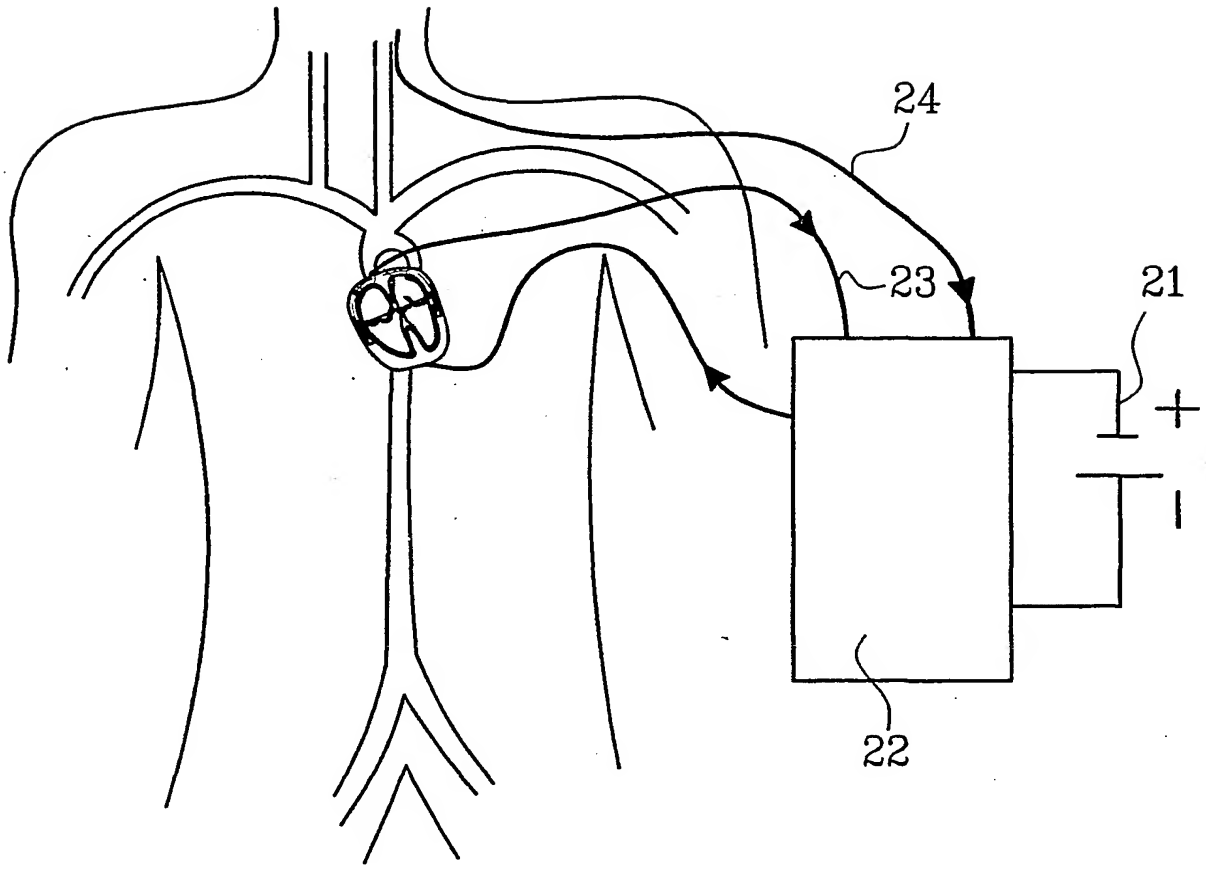


FIG.4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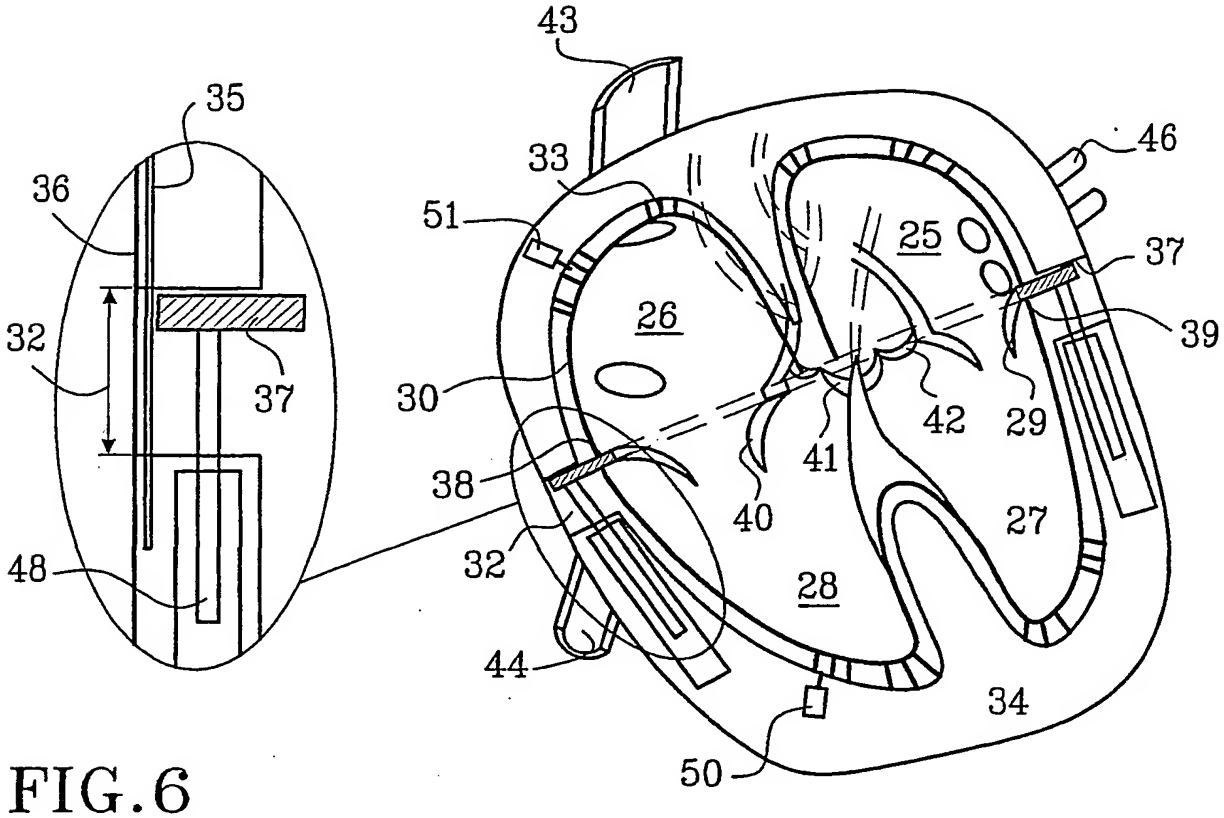
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FIG.6

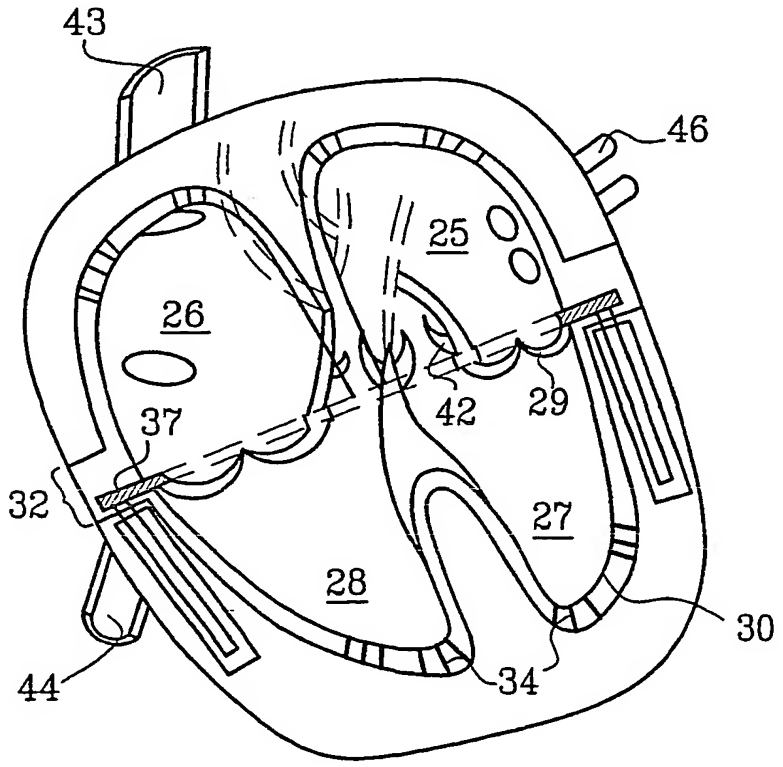
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FIG.7

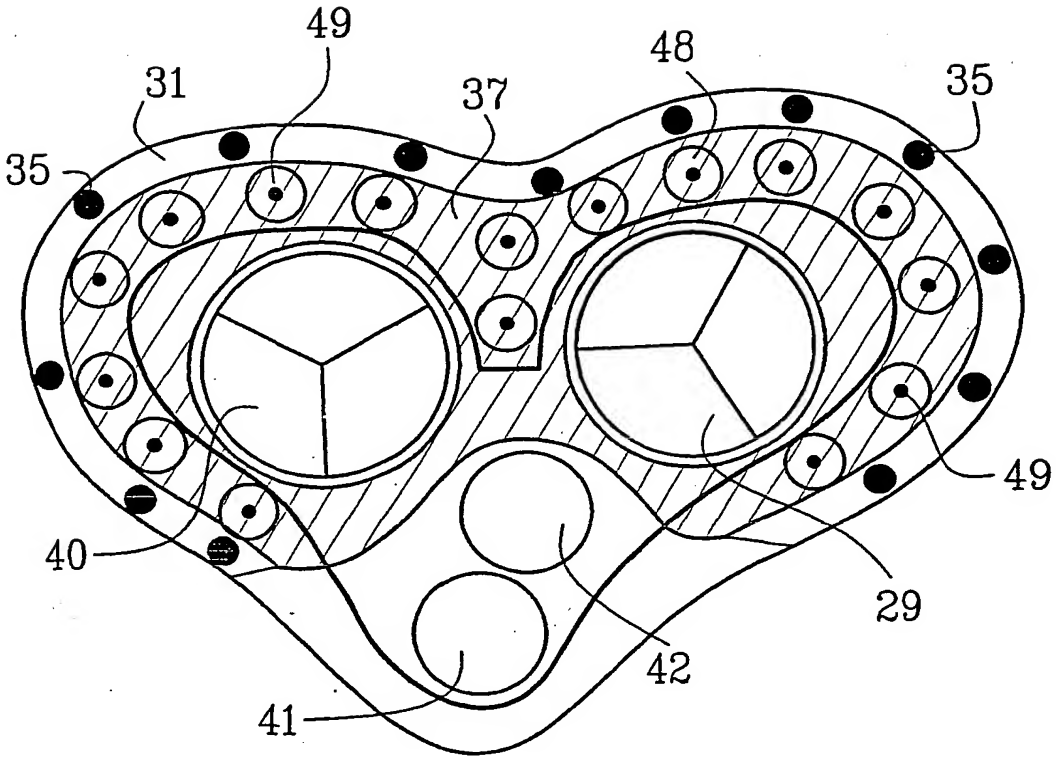

FIG.8

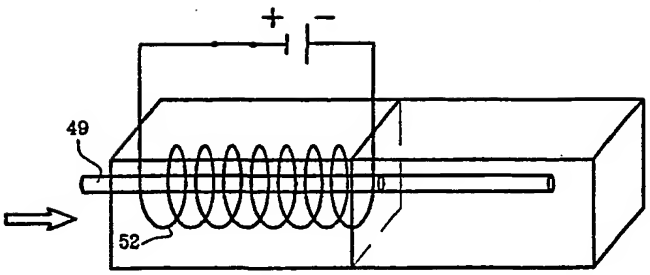

FIG.9

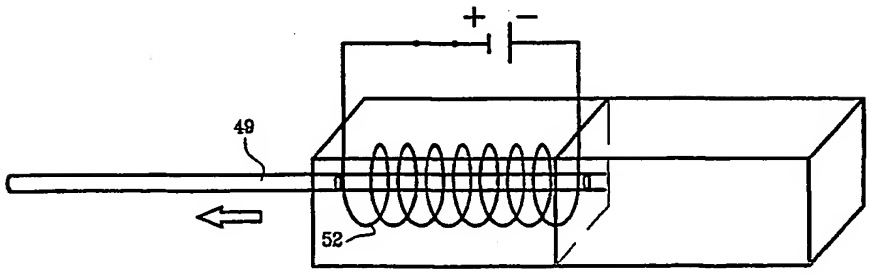

FIG.10

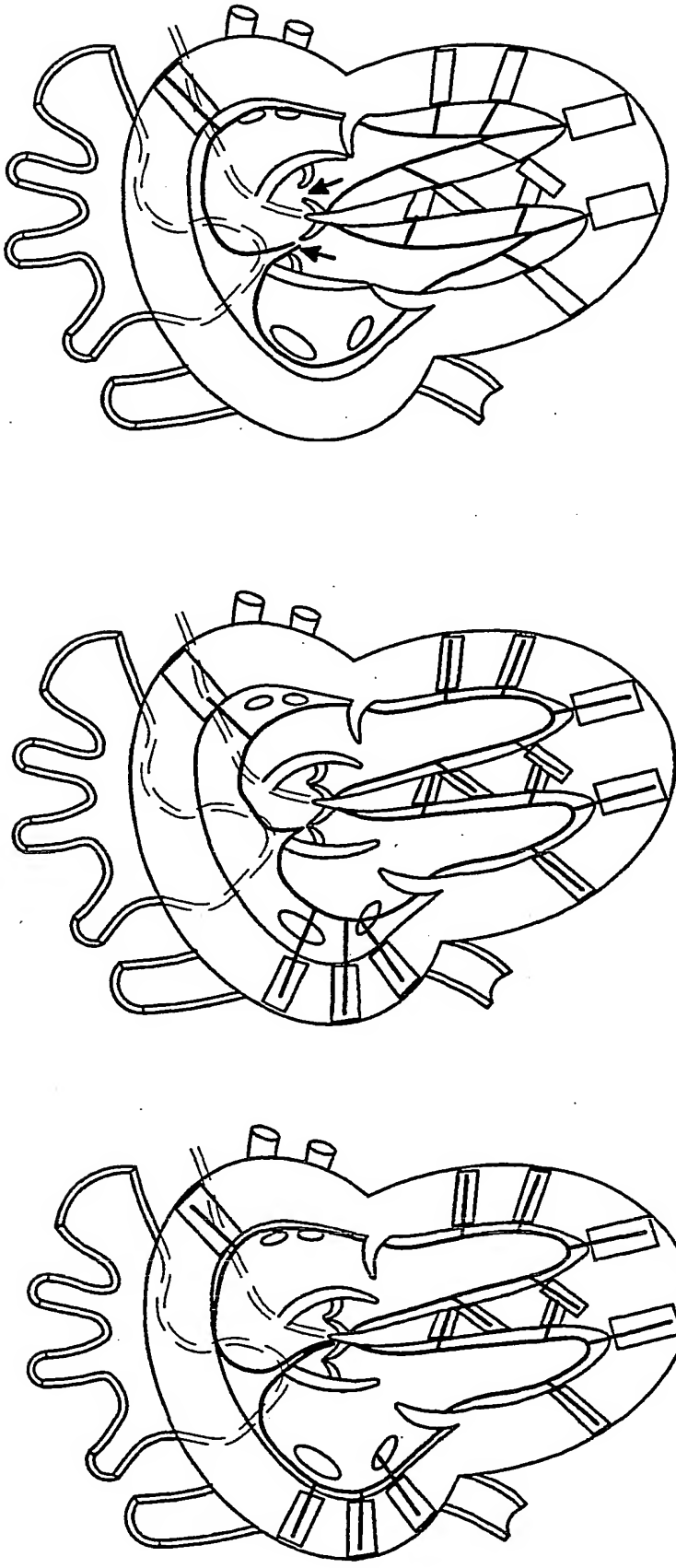

FIG. 12

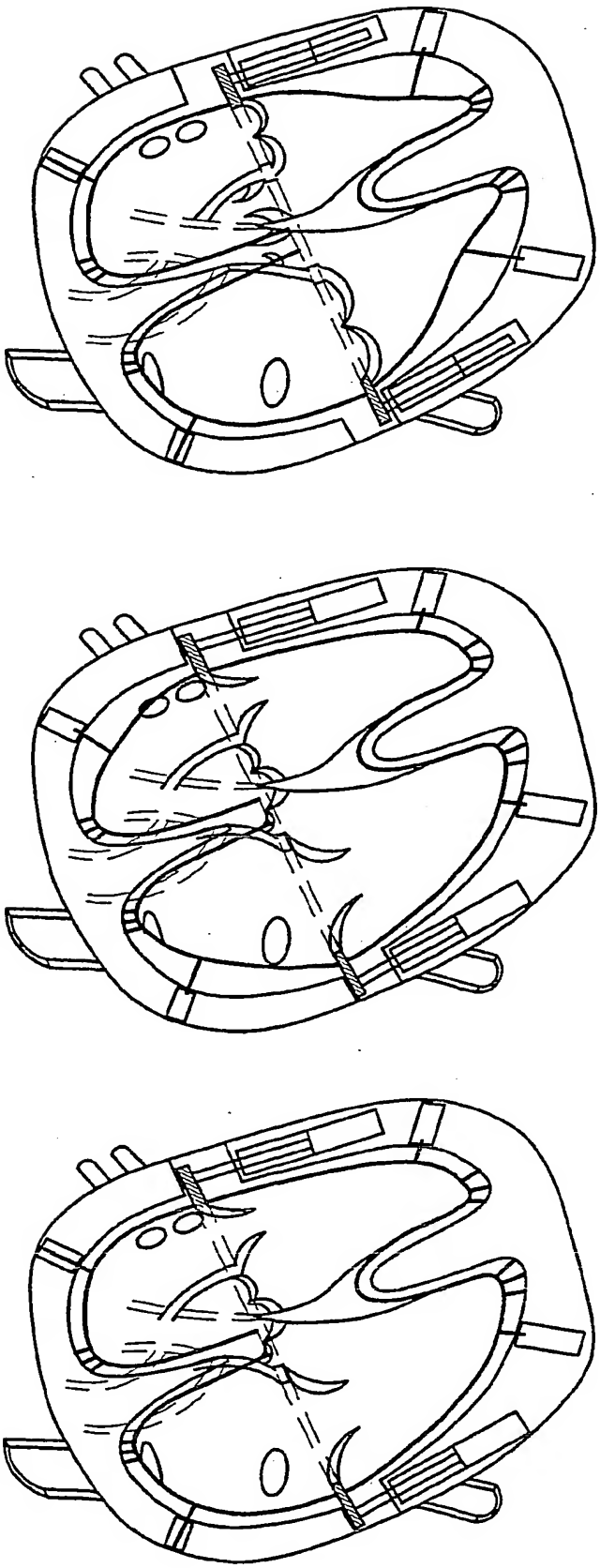

FIG.11

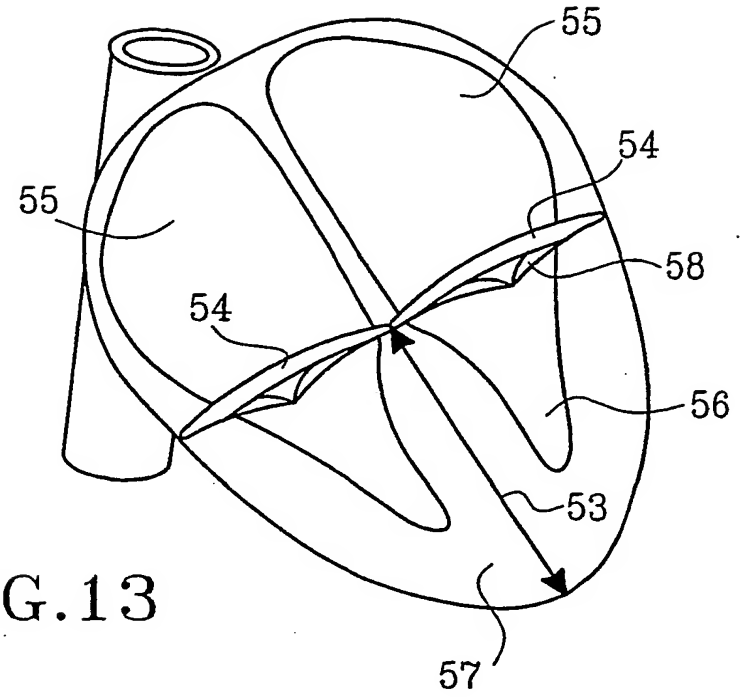

FIG.13

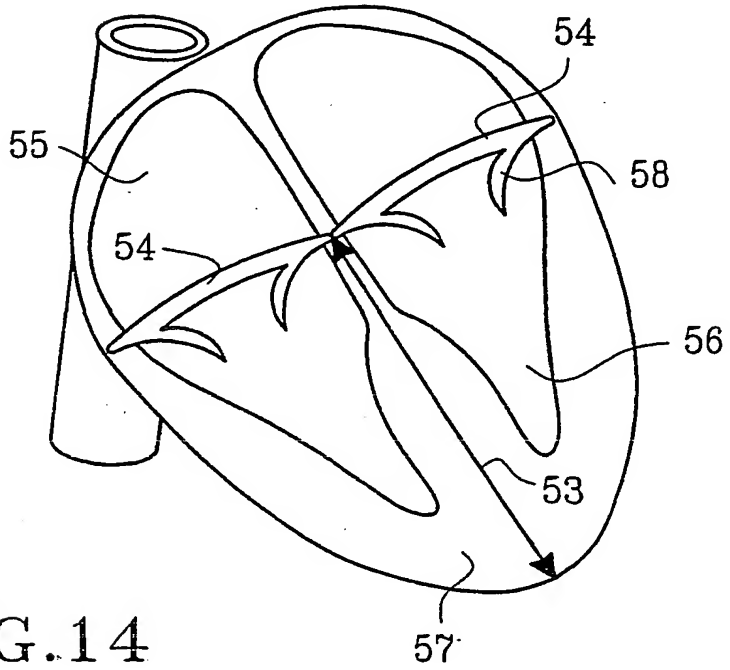

FIG.14

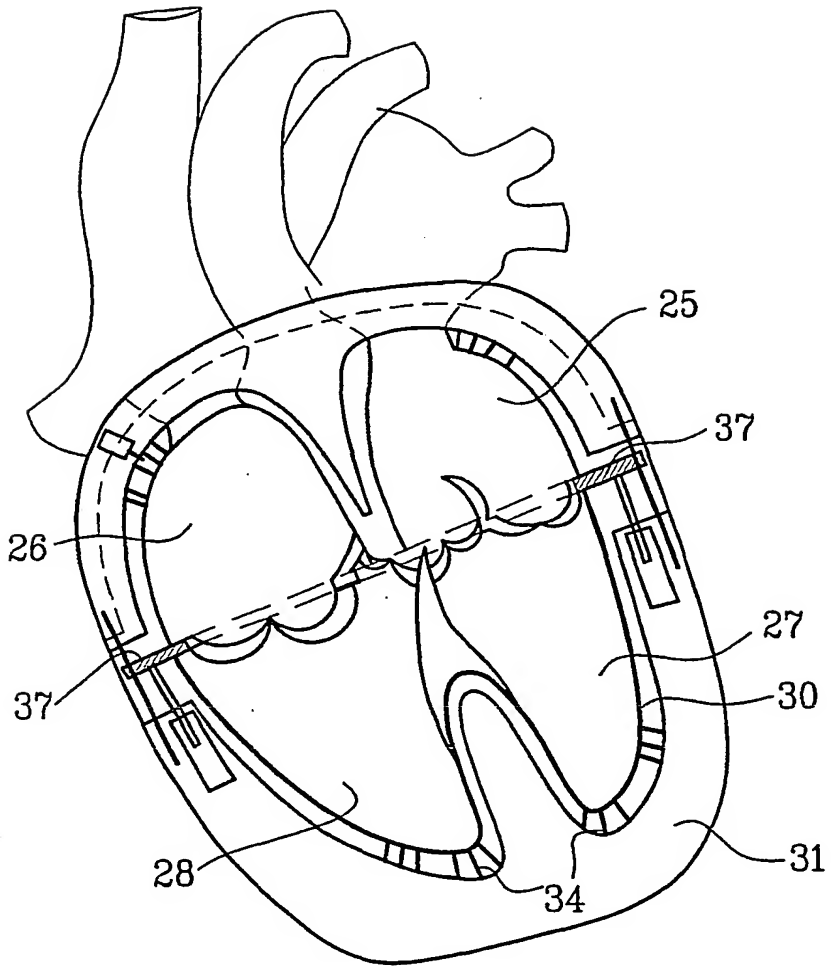

FIG.15

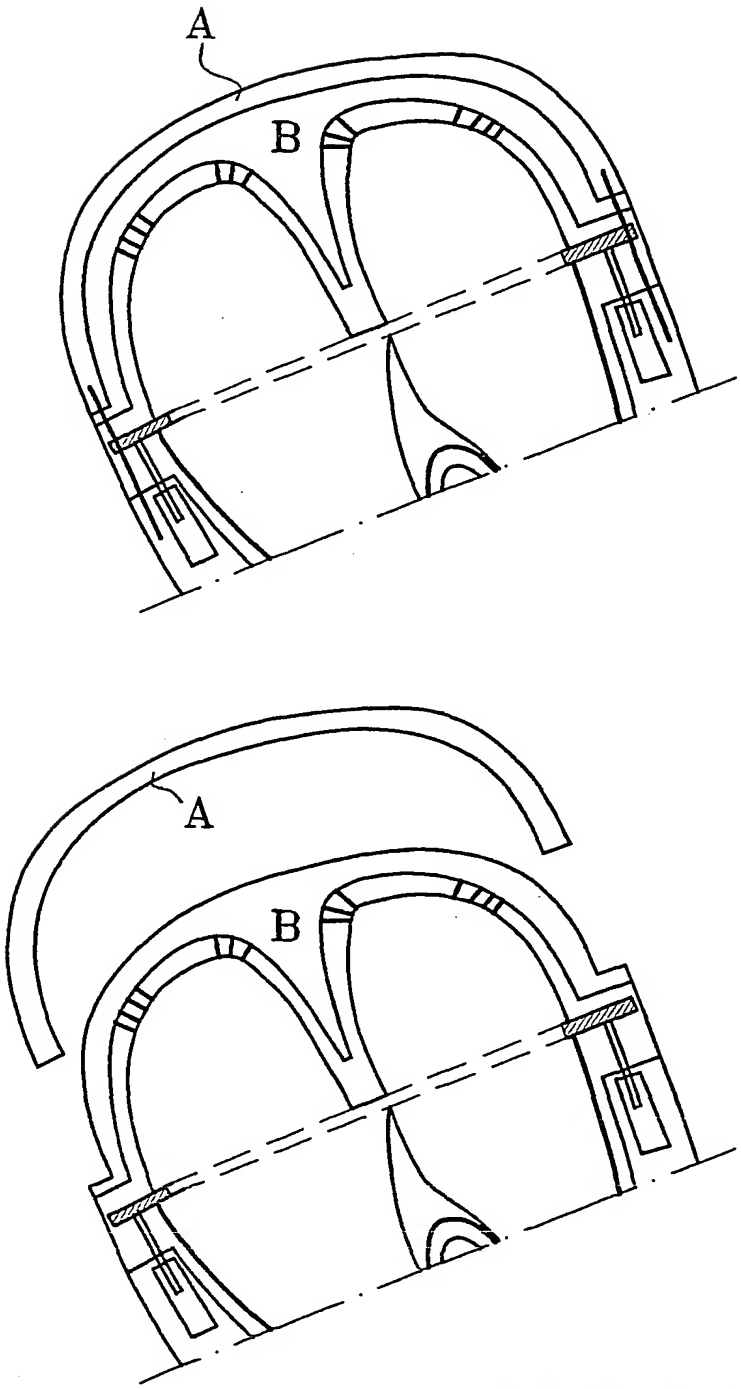

FIG. 16

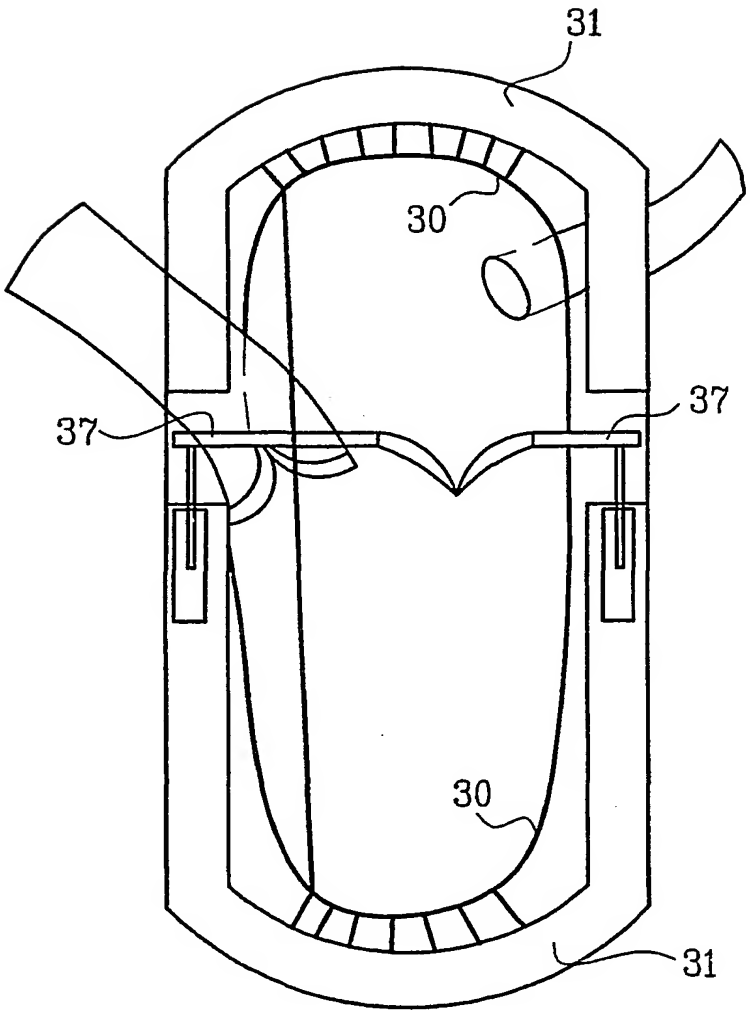

FIG. 17

INTERNATIONAL SEARCH REPORT

International application No.
PCT/SE 02/00689

A. CLASSIFICATION OF SUBJECT MATTER

IPC7: A61M 1/10
According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC7: A61M

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

SE,DK,FI,NO classes as above

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 5135539 A (CARPENTIER), 4 August 1992 (04.08.92), figures 1-2, claims 1-14	1
X	FR 2710847 A1 (DEMANDEUR(S)), 14 April 1995 (14.04.95), figures 1,2, claims 1-5	1
A	US 6123724 A (DENKER), 26 Sept 2000 (26.09.00), figures 1-4, claims 1-17	1-8
A	US 6099460 A (DENKER), 8 August 2000 (08.08.00), figures 1-6, claims 1-31	1-8

[X] Further documents are listed in the continuation of Box C. [X] See patent family annex.

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"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
12 June 2002	09-07-2002
Name and mailing address of the ISA Swedish Patent Office Box 5055, S-102 42 STOCKHOLM Facsimile No. +46 8 666 02 86	Authorized officer Agneta Änggård/SN Telephone No. +46 8 782 25 00

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INTERNATIONAL SEARCH REPORT

International application No.
PCT/SE 02/00689

C (Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US 5139517 A (CORRAL), 18 August 1992 (18.08.92), figures 1-4C, claims 1-12 --	1-8
A	US 4809676 A (FREEMAN), 7 March 1989 (07.03.89), figures 1-2, claims 1-20 -- --------	1-8

INTERNATIONAL SEARCH REPORT

Information on patent family members

01/05/02

International application No.
PCT/SE 02/00689

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US 4809676 A	07/03/89	NONE	